EXHIBIT 2

UNITED STATES BANKRUPTCY COURT
WESTERN DISTRICT OF NORTH CAROLINA
CHARLOTTE DIVISION

In re LTL MANAGEMENT LLC,[1] Debtor.	Chapter 11 Case No. 21-30589 (JCW)

INFORMATIONAL BRIEF OF LTL MANAGEMENT LLC

Gregory M. Gordon
Dan B. Prieto
Amanda Rush
JONES DAY
2727 N. Harwood Street
Dallas, Texas 75201

Brad B. Erens
Caitlin K. Cahow
JONES DAY
77 West Wacker
Chicago, Illinois 60601

C. Richard Rayburn, Jr.
John R. Miller, Jr.
RAYBURN COOPER & DURHAM, P.A.
227 West Trade Street, Suite 1200
Charlotte, North Carolina 28202

Kristen R. Fournier
KING & SPALDING LLP
1185 Avenue of the Americas
34th Floor
New York, NY 10036

Kathleen A. Frazier
SHOOK, HARDY & BACON L.L.P.
JPMorgan Chase Tower
600 Travis Street, Suite 3400
Houston, TX 77002

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[1] The last four digits of the Debtor's taxpayer identification number are 6622. The Debtor's address is 501 George Street, New Brunswick, New Jersey 08933.

TABLE OF CONTENTS

Page

TABLE OF CONTENTS
(continued)

Page

I. Introduction

LTL Management LLC—the debtor in this chapter 11 case (the "Debtor" or "LTL")[2] and an indirect subsidiary of Johnson & Johnson ("J&J")—files this chapter 11 case to resolve permanently all mass tort claims relating to its cosmetic talc products in a manner that is efficient and equitable to all parties, including current and future claimants. Specifically, the Debtor seeks to confirm as promptly as possible a chapter 11 plan of reorganization that establishes a trust to efficiently process and pay such claims—notwithstanding that the Debtor continues to stand behind the safety of its cosmetic talc and does not believe the claims have merit.

The unfortunate reality is that this filing is necessitated by an unrelenting assault by the plaintiff trial bar, premised on the false allegations that the Debtor's 100+ year old talc products contain asbestos and cause cancer. These litigation-created allegations lack any scientific support and have been disavowed for decades by independent experts, as well as governmental and regulatory bodies. Unsurprisingly, therefore, the Debtor's predecessor—Johnson & Johnson Consumer Inc. ("Old JJCI")[3]—ultimately prevailed in the majority of talc cases it tried. Yet—due to the well-documented abuses that occur in the state court tort system and an inability to secure review by the U.S. Supreme Court—Old JJCI and J&J were subject intermittently to extraordinary judgments, including a $4.69 billion verdict—the fifth largest personal injury

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[2] A comprehensive description of the Debtor, its history, its assets and liabilities and the events leading to the commencement of this chapter 11 case can be found in the declaration of John K. Kim (the "First Day Declaration"), which was filed contemporaneously herewith.

[3] In 1979, J&J stopped manufacturing JOHNSON'S® Baby Powder and the manufacturing operations instead were transferred to Old JJCI (or its predecessors), at which time Old JJCI assumed from J&J all liabilities associated with the business. Nevertheless, J&J continued to be named as a defendant in cosmetic talc litigation. In light of these facts, this Informational Brief refers to J&J and/or Old JJCI, where appropriate.

verdict in the history of the United States[4]—awarded to just 22 plaintiffs whose claims a state court wrongly permitted to be consolidated into a single trial."[5] In 2021 alone, Old JJCI and J&J were victorious in the six cases that have gone to a jury verdict (one of which was a three plaintiff consolidation), but suffered two adverse verdicts in which the jury awarded upwards of $26 million to one plaintiff and $27 million to the other. The incongruity of those two adverse verdicts is telling. In the first, the jury awarded $25 million in compensatory damages and a nominal $100,000 in punitive damages. In the second, the jury awarded the inverse, just shy of $2.5 million in compensatory damages and $25 million in punitive damages.

If only a small fraction of the pending cases continued to yield such inconsistent and excessive awards, the assets available to pay current and future claimants could have been exhausted. And the costs associated with the continued litigation of the claims for decades to come would have been simply unsustainable. The *status quo* therefore was untenable, and this chapter 11 case is necessary to appropriately assess, resolve, and administer these claims in an efficient and equitable manner.

Prior to the filing of this chapter 11 case, Old JJCI engaged in a Texas divisional merger. As a result of that divisional merger, Old JJCI ceased to exist and the Debtor and Johnson & Johnson Consumer Inc. ("New JJCI") were created. Through the divisional merger, the Debtor was allocated talc-related liabilities of Old JJCI and certain assets, including the shares of

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4 *See, e.g.*, *10 of the Largest Personal Injury Verdicts & Settlements in History*, Oasis Financial, *available at* https://www.oasisfinancial.com/largest-personal-injury-verdicts-settlements-in-history/.

5 *See Ingham v. Johnson & Johnson*, 608 S.W.3d 663, 680 (Mo. App. 2020). The total compensatory award was $550 million, with a punitive award for $4.14 billion. *Id.* This punitive damages award was later reduced on appeal to approximately $1.6 billion. *Id.* at 724-25. And, the appellate court ultimately reversed the decision with respect to two plaintiffs. *Id.* at 693-94.

Royalty A&M LLC, which has a royalty management and finance business. New JJCI was allocated the remaining assets and liabilities of Old JJCI.

To promote a prompt resolution of this case and avoid unnecessary litigation regarding alleged harm suffered by claimants as a result of the divisional merger (there was none),[6] Old JJCI and J&J have taken a number of steps to ensure that the financial interests of claimants are fully protected. First, the Debtor's ability to pay claims is supported by a funding agreement with both New JJCI and J&J, as joint obligors, for the full amount of the value of New JJCI. J&J's inclusion in the funding agreement should put to rest any concerns regarding the divisional merger or any hypothetical JJCI intercompany transactions, including issuance of dividends or forgiveness of intercompany debt, that could potentially diminish New JJCI's assets during the course of this chapter 11 case. Second, J&J and New JJCI have agreed to advance an aggregate amount of $2 billion under the funding agreement into a qualified settlement fund for the payment of cosmetic talc claims. These funds will be dedicated exclusively for use in paying such claims. Although the Debtor and J&J strongly believe $2 billion is substantially in excess of any liability the Debtor should have, J&J and New JJCI have made this commitment to eliminate any doubt regarding the Debtor's financial ability to pay legitimate claims. Third, the Debtor received an equity interest in Royalty A&M LLC, which operates a royalty management and finance business that has royalty streams with a present value of over $350 million. Royalty A&M LLC plans to grow this business by periodically reinvesting the income from these royalties in exchange for additional royalties.

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6 Prior to the commencement of this case, on three separate occasions, claimants alleged that any divisional merger undertaken by Old JJCI regardless of its terms would constitute a fraudulent transfer and sought to enjoin Old JJCI from undertaking it. The relief was denied by the United States Bankruptcy Court for the District of Delaware and the Superior Court of New Jersey, and plaintiffs sought and then withdrew the request for such an injunction in Missouri federal court.

Simply put, there can be no legitimate argument that the divisional merger prejudiced claimants. Through the funding agreement, both J&J and New JJCI are standing behind the Debtor's responsibility for cosmetic talc claims, up to the value of New JJCI. In addition, J&J and New JJCI have agreed to advance $2 billion under the funding agreement for deposit into a qualified settlement fund dedicated exclusively to the payment of cosmetic talc claims. And these funding commitments are further buttressed by Royalty A&M LLC's operating business with assets in excess of $350 million. In sum, the Debtor undeniably has more than sufficient funding to pay any legitimate cosmetic talc claims.

The cosmetic talc claims for which the Debtor seeks a complete resolution mainly target JOHNSON'S® Baby Powder (hereinafter, "Johnson's Baby Powder") as a purported cause of ovarian cancer and mesothelioma. But Johnson's Baby Powder has been a staple for hundreds of millions of people for over 125 years. If claimants' allegations were correct that the product causes disease, there should have been long ago an epidemic clearly attributed to the use of the product. That is not the case.

To the contrary, the timing of the claims highlights their lack of merit. Questions regarding whether Johnson's Baby Powder contained asbestos and whether use of cosmetic talcum powder could cause ovarian cancer were raised as early as the 1970s and 1980s, respectively. Such allegations have been investigated by the Food & Drug Administration (the "FDA"),[7] among others, and found to be unsupported by fact or science. Few cosmetic talc cases were filed until the mid-2010s when plaintiffs' counsel, looking for a new solvent

[7] *See, e.g.,* 7/11/1986 Letter from J.W. Swanson, Acting Associate Commissioner for Regulatory Affairs, U.S. Food and Drug Administration, to P. Douillet with enclosures re: Petition Requesting that Cosmetic Talc be Labeled with and Asbestos Warning Statement, and related correspondence [Recently identified on publicly filed exhibit list in *Prudencio* as DX-17214]; 4/1/2014 FDA's 2014 denial of Citizen's Petition requesting warning on talcum powder products and related correspondence [Recently identified on publicly filed exhibit list in *Prudencio* as DX-17456].

"asbestos" defendant after most had left the tort system, revived the decades-old allegations to advance the current claims pending against the Debtor.

Unlike the debtors in typical asbestos mass-tort bankruptcy cases, Old JJCI never manufactured a product that contained asbestos. Regardless, and despite the absence of legitimate scientific support, plaintiffs have alleged that Old JJCI's cosmetic talc products contained asbestos and cause mesothelioma or ovarian cancer. But as a New Jersey appellate court recently held, plaintiffs' expert opinions regarding Old JJCI's cosmetic talc products and their alleged health effects should have been excluded as lacking the requisite scientific rigor and analysis, and their proffer inevitably would (and did) confuse jurors.[8]

Moreover, in the absence of science to support claims that Old JJCI's talcum powder products caused ovarian cancer and mesothelioma, as well as other diseases, the plaintiff bar has developed alternative disingenuous strategies to advance such claims. These strategies have included plaintiff experts' contrived "scientific" discoveries purportedly showing the presence of trace amounts of "asbestos" in the talcum powder products; trial by media through misinformation campaigns launched via news articles, planted medical literature, advertising, and lobbying efforts; and prejudicial litigation tactics, including forum shopping and consolidation of multiple plaintiffs in a single trial to obfuscate causation issues.[9]

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8 *See Lanzo v. Cyprus Amax Minerals Co., et al.*, 467 N.J. Super. 476, 510-18 (App. Div. 2021).

9 Plaintiffs' counsel has amassed vast listings of individuals diagnosed with ovarian cancer or mesothelioma. These lists were then used to assert claims against Old JJCI and J&J in an effort to coerce settlement. As a plaintiff's counsel recently was forced to concede under oath, certain plaintiffs' counsel took the list and asserted claims against Old JJCI and J&J without even assessing whether the claimants had been exposed to the talc used in Johnson's Baby Powder, and in some cases, pursued such claims even though the claimant had previously alleged and recovered on a theory that the disease was exclusively attributable to other products. *See* 9/20/2021 telephonic hearing transcript in *In re Imerys Talc America, Inc.*, (D. Del. Bankruptcy Ct., No. 19-10289-LSS) at 52:1-56:15, 60:16-22, 63:11-64:2, 66:10-67:10, 67:22-68:19.

These tactics have led to a few blockbuster plaintiff verdicts, with extreme and duplicative punitive damages awards, in plaintiff-friendly jurisdictions. While many of these extraordinary verdicts have been reversed on appeal, such reversals have done little to temper the now booming cosmetic talc litigation industry. Rather, each plaintiff verdict has resulted in substantial media attention and inevitably inspired the filing of more cases. That deluge of cases has resulted in astronomical costs, with Old JJCI having incurred nearly $1 billion in defense costs on account of cosmetic talc litigation, nearly all of which has been spent in only the last five years. This does not account for payments for settlements and verdicts, which have totaled approximately $3.5 billion. The ubiquity of Old JJCI's products, the relative prevalence of ovarian cancer, and the extended latency period for mesothelioma—and allegedly also for ovarian cancer—ensure that the Debtor will continue to be sued for decades, regardless of its liability. The prospect that defense spending will continue apace, or even accelerate, coupled with the unpredictability of astronomical verdicts, necessitated the commencement of this case. Indeed, the wildly-divergent verdicts across cases resulted in claimants with the same alleged injury receiving substantially disparate treatment, an unfortunate and well-chronicled deficiency of the tort system.

This chapter 11 case appropriately affords the parties an efficient and certain pathway to resolve all current and future cosmetic talc claims, while allowing New JJCI, J&J, and its affiliates to operate their businesses and continue to develop, manufacture, and distribute lifesaving therapies and devices. This is unquestionably a proper objective of a chapter 11 case.[10] J&J is a global innovator and leader in public health and has been at the forefront of

[10] *See e.g., In re Bestwall LLC*, 605 B.R. 43, 49 (Bankr. W.D.N.C. 2019) ("Attempting to resolve asbestos claims through 11 U.S.C. § 524(g) is a valid reorganizational purpose, and filing for Chapter 11, especially in the context of an asbestos or mass tort case, need not be due to insolvency.").

healthcare innovation for over 130 years. That innovation includes novel oncology, immunology, and vaccine products, including its COVID-19 vaccine that it developed and supplied at non-profit pricing. The applicable provisions of the Bankruptcy Code are the only means available for companies, like the Debtor, that are plagued by massive numbers of tort claims, to permanently resolve those claims in a manner that is fair and equitable to all parties, including current and future claimants.

The global and equitable resolution of similarly-situated claimants is a hallmark of the chapter 11 process. These resolutions have been achieved in over 60 asbestos and other mass tort bankruptcy cases, where trusts have been established to efficiently and equitably compensate current and future claims based on uniform sets of criteria for similar claims. These trusts have been recognized as a resounding improvement on the tort system. As the Third Circuit explained in *Federal-Mogul*:

> [T]he trusts appear to have fulfilled Congress's expectation that they would serve the interests of both current and future asbestos claimants and corporations saddled with asbestos liability. In particular, observers have noted the trusts' effectiveness in remedying some of the intractable pathologies of asbestos litigation, especially given the continued lack of a viable alternative providing a just and comprehensive resolution.

See In re Federal-Mogul Global, Inc., 684 F.3d 355, 362 (3d Cir. 2012) (citing studies).

In the absence of this chapter 11 filing, the Debtor anticipates that it could soon be spending hundreds of millions of dollars per year in defense costs alone, in addition to settlements and verdicts which, if history is any indicator, would range dramatically in magnitude, regardless of any actual liability.

This Informational Brief provides an overview of Old JJCI cosmetic talc products and issues underlying the current tidal wave of cosmetic talc litigation. It describes the history of and science surrounding the safety of cosmetic talc, including Old JJCI products, as well as the

radically upward trajectory of cosmetic talc litigation itself, and the challenges that litigation posed to the Debtor. Finally, this Informational Brief provides a brief overview of the Debtor's goals in this case.

II. Decades of Studies and Testing Showing that J&J's/Old JJCI's Talcum Powder Products Are Safe

A. Background on Talc

Talc is a naturally occurring mineral—the softest mineral on earth—and is composed of magnesium, silicon, oxygen, and hydrogen.[11] It is found in rock deposits all over the world, including Canada, China, South Korea, India, the United States, Brazil, France, and Japan, where it is mined like many other minerals.[12] While some talc deposits are relatively pure, others may also contain various "accessory" minerals, depending on the geographic location, age, and temperature of the ore body, as well as other conditions during formation.[13] As a result, talc from different locations—even those in close proximity—may have very different mineral profiles and characteristics.[14]

Talc is "inert," meaning it does not generate a chemical reaction when ingested or used on the skin, and is known for its fragrance retention, luster, purity, softness, whiteness, high dielectric strength and thermal conductivity, low electrical conductivity, and oil and grease

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11 USGS Fact Sheet 0065-00, *Industrial Minerals of the United States: U.S. Talc—Baby Powder and Much More*, U.S. GEOLOGICAL SURVEY (SEPT. 2000) ("USGS Fact Sheet 0065-00"), *available at* https://pubs.usgs.gov/fs/fs-0065-00/fs-0065-00.pdf.

12 *See, e.g.*, *Mineral Commodity Summaries: Talc and Pyrophyllite Statistics and Information*, U.S. GEOLOGICAL SURVEY (Jan. 2021) ("USGS Mineral Commodity Summaries 2021"), *available at* https://pubs.usgs.gov/periodicals/mcs2021/mcs2021-talc.pdf.

13 USGS Fact Sheet 0065-00.

14 *See e.g.,* IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. Volume 93: Carbon Black, Titanium Dioxide, and Talc. Lyon, France: International Agency for Research on Cancer (2010) (the "IARC 2010 Monograph") at 284, *available at* https://monographs.iarc.who.int/wp-content/uploads/2018/06/mono93.pdf.

adsorption.[15] Due to these commercially useful properties, talc can be found in numerous products that are used by many people every day, such as soap, deodorant, make-up, and tablets.[16]

After mining, talc is partially crushed and initially sorted according to "grades" based on whiteness and conformity with specifications.[17] The best grades, including what ultimately becomes talcum powder, are produced through special mining and sorting operations.[18] Non-talc materials in the talc may have an undesirable effect on the color of the talcum powder, its softness, lubricity, or its moisture-adsorbing properties.[19] Thus, as part of the process of manufacturing talcum powder, non-talc minerals are removed using a variety of processes, including wash or "beneficiation" processes, hand sorting, washing and froth flotation, or magnetic separation.[20]

Talcum powder marketed in the United States is normally more than 95% "pure," which qualifies it for use in cosmetics and other personal care products, including baby and body products.[21] These products take advantage of talcum powder's ability to adsorb moisture, oils, and odor, lubricate, prevent "caking," make products like facial makeup opaque, or improve the

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15 USGS Fact Sheet 0065-00.

16 *Id.*

17 *See, e.g.*, Zazenski, R, et al., *Talc: Occurrence, Characterization, and Consumer Applications*, REGUL. TOXICOL. PHARMACOL., 21:218-229 (1995) ("Zazenski 1995") at 219-220; *see also* Fiume, MM et al., *Safety Assessment of Talc as Used in Cosmetics*, INT'L. J. OF TOX., 34(Supp. 1):66S-129S (2015) ("Fiume 2015") at 69S; 2/25/2019 Expert Report of Dr. Mary Poulton, Ph.D. for General Causation *Daubert* Hearing in *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs. & Prods. Liab. Litig.*, (D.N.J. MDL No. 16-2738 (FLW) (LHG)), Dkt. 9740-31 ("Poulton Rep.") at § III.

18 *See, e.g.*, Zazenski 1995 at 219-220; *see also* Poulton Rep. at § III.

19 *See, e.g.*, Zazenski 1995 at 219-220.

20 *See, e.g.*, Zazenski 1995 at 219-220; *see also* Fiume 2015 at 70S; Poulton Rep. at § III.

21 *See, e.g.*, Zazenski 1995 at 219-220; *see also* IARC 2010 Monograph at 278.

"feel" of a product.[22] Talc ores of sufficient purity to ultimately become talcum powder are not common, and so such cosmetic talc, which makes up only approximately 5% of all talc used commercially (the rest generally being referred to as "industrial talc"), is mined in only a few places.[23] Since 1946, three sources of cosmetic talc have been used by J&J or Old JJCI to manufacture talcum powder products sold in North America: the Fontana mine in the Val Germanasca region of Northern Italy, several mines in Vermont, and the Jizhua (also known as Zhizhu) mine in the Guangxi province in southern China.

B. Johnson's Baby Powder

Cosmetic talc litigation against the Debtor has focused primarily, though not exclusively, on Johnson's Baby Powder.[24] Johnson's Baby Powder is made up of over 99% cosmetic-grade talcum powder, with small amounts of additional ingredients for fragrance. Johnson's Baby Powder—advertised "for toilet and nursery"—went on the market in 1894, launching the company's baby care line of products. For over 125 years Johnson's Baby Powder has been used by hundreds of millions of consumers worldwide.

On May 19, 2020, Old JJCI announced it would permanently discontinue its line of talc-based Johnson's Baby Powder in the U.S. and Canada. The decision was based on business considerations, including misinformation about the safety of the company's talc-based Johnson's

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22 *See, e.g.*, Zazenski 1995 at 221-224; *What is talc?*, Industrial Minerals Association - North America, *available at:* https://www.ima-na.org/page/what_is_talc.

23 *See, e.g.,* USGS Mineral Commodity Summaries 2021 ("industrial" grade talc can be found in products such as paint, paper, plastics, rubber, and roofing materials); *see also* 2/25/2019 Expert Report of Dr. Laura Webb, Ph.D. for General Causation *Daubert* Hearing in *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs. & Prods. Liab. Litig.,* (D.N.J. MDL No. 16-2738 (FLW) (LHG)), Dkt. 9740-28 at § 4.0.

24 Certain claims have identified "Shower to Shower," a talc-based deodorizing product that was previously produced by J&J/Old JJCI before being sold to a competitor in 2012. In general, when referenced by claimants, Shower to Shower is treated interchangeably with Johnson's Baby Powder because both are cosmetic products that contain talc as a primary or major ingredient.

Baby Powder disseminated by the plaintiff bar. As stated in the press release for the announcement, the company "remains steadfastly confident in the [product's] safety[,]" but the "[d]emand for talc-based Johnson's Baby Powder in North America has been declining due in large part to changes in consumer habits and fueled by misinformation around the safety of the product and a constant barrage of litigation advertising."[25]

C. The Risk of Cancer from Talcum Powder Due to Alleged Asbestos Contamination Was First Raised and Put to Rest in the 1970s.

"Asbestos" is a term describing a group of six minerals that, under certain rare geological conditions, can form in bundles composed of long, thin, extremely flexible fibers with high tensile strength. When the six minerals form in this unique way,[26] they are "asbestiform," when they do not, they are "nonasbestiform."[27] In other words, there is an asbestiform and a (much more common) nonasbestiform version of each of the six minerals.[28] Every federal regulation or statute defines asbestos as the asbestiform variety of the six minerals.[29] The six relevant minerals come from two mineral families: "serpentine" and "amphibole."[30]

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25 *Johnson & Johnson Consumer Health Announces Discontinuation of Talc-based Johnson's Baby Powder in U.S. and Canada*, JOHNSON & JOHNSON (May 19, 2020), *available at* https://www.jnj.com/our-company/johnson-johnson-consumer-health-announces-discontinuation-of-talc-based-johnsons-baby-powder-in-u-s-and-canada.

26 The way a mineral forms in nature is called its "habit." IARC 2010 Monograph at 277 ("[A]sbestiform describes the pattern of growth of a mineral that is referred to as a 'habit'").

27 As IARC explains, the term asbestos "describes six minerals that occur in the asbestiform habit" and only "when asbestiform, [do] they constitute asbestos." *Id*. The National Institute for Occupational Safety and Health ("NIOSH") similarly declared that "nonasbestiform minerals are not 'asbestos' or 'asbestos minerals.'" Nat'l Inst. for Occupational Health and Safety, *Asbestos Fibers and Other Elongate Mineral Particles: State of the Science and Roadmap for Research* 7-8 (2011) ("NIOSH Roadmap") at vii.

28 IARC 2010 Monograph at 277, 411-413; 40 C.F.R. § 763 Subpt. E, App. E, Table 2-1.

29 *See* 29 C.F.R. § 1910.1001(b) (OSHA); 40 C.F.R. § 763.163 (EPA); 40 C.F.R. § 61.141 (EPA); 30 C.F.R. § 56.5001(b) (MSHA); 73 Fed. Reg. 11284, 11292 (2008) (MSHA); 15 U.S.C. § 2642(3) (Toxic Substances Control Act).

30 The mineral family "amphibole" does not automatically mean "asbestos."

Mineral Family	Nonasbestiform	Asbestiform
Serpentine	Antigorite/Lizardite	Chrysotile
Amphibole	Riebeckite	Crocidolite
Amphibole	Grunerite-Cummingtonite	Amosite
Amphibole	Tremolite	Tremolite Asbestos
Amphibole	Anthophyllite	Anthophyllite Asbestos
Amphibole	Actinolite	Actinolite Asbestos

As the chart above demonstrates, the asbestiform and nonasbestiform varieties of the same mineral sometimes have similar names, and sometimes entirely different names. For example, riebeckite is the non-asbestos version of crocidolite. In contrast, there are asbestos types of tremolite, and non-asbestos types of tremolite. And, though they have the same chemical composition, the two look very different because of the different geological conditions in which they were formed[31]:

Non-Asbestiform Tremolite

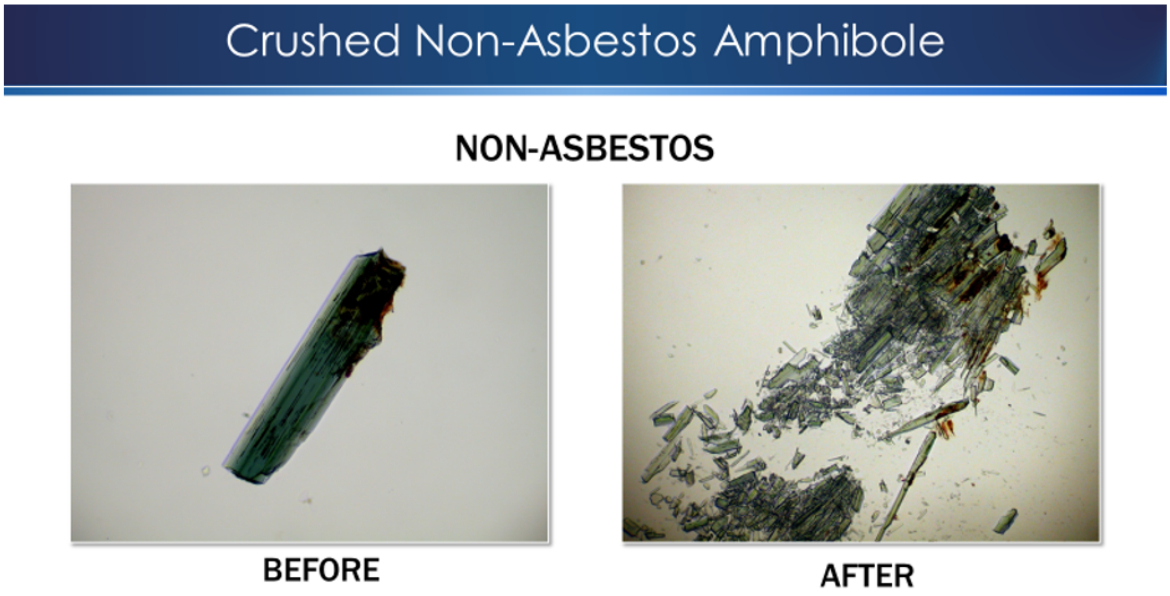
Asbestiform Tremolite

These two types of tremolite are typically distinguished by referring to the nonasbestiform variety as simply "tremolite," while referring to the asbestiform variety as "asbestiform tremolite" or "tremolite asbestos."

A "fiber" is often defined as any mineral particle that is long and thin, no matter how it

[31] Campbell, W. J., R. L. Blake, L. L. Brown, E. E. Cather, and J. J. Sjoberg. 1977. Selected Silicate Minerals and Their Asbestiform Varieties: Mineralogical Definitions and Identification-Characterization. Information Circular 8751. Washington, D.C.: U.S. Department of the Interior, U.S. Bureau of Mines Report of Investigations at 7.

formed in nature. Usually, to be a "fiber," a particle must meet certain size and shape criteria; such as a minimum length and an aspect ratio of greater than 5:1 (*i.e.*, over five times longer than it is wide).[32] These size and shape parameters are sometimes called "counting criteria." Just because a particle meets the counting criteria for a "fiber" does not mean it is "asbestos."[33] When nonasbestiform minerals are broken up, the resulting particles are often called "cleavage fragments."[34]



Cleavage fragments can at times be long and thin, and so can resemble asbestos. Those particles may also meet the size and shape criteria of a "fiber," but they are still not asbestos.[35]

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32 *See, e.g.*, 40 C.F.R. § 763 app. A § II.A.9.

33 IARC 2010 Monograph at 277.

34 *See* U.S. Mine Safety and Health Administration ("MSHA"): Asbestos Exposure Limit. 73 Fed. Reg. 11284, 11285 (Feb. 29, 2008) ("When pressure is applied, the nonasbestiform crystals fracture into prismatic particles, which are called cleavage fragments because they result from the particle's breaking or cleavage. Cleavage fragments may be formed when nonfibrous minerals are crushed, as may occur in mining and milling operations.").

35 *See e.g.,* IARC 2010 Monograph at 277 (explaining that, "when not asbestiform, [the six minerals] are referred to as mineral fragments or cleavage fragments," which minerals "may also be elongated without being asbestiform."). The plaintiff bar is well aware of this distinction. *See e.g.,* 3/5/2019 Dr. William Longo trial testimony in *Rimondi et al. v. BASF Catalysts LLC, et al.,* (Super. Ct. N.J., Middlesex Cnty.,

Concerns over exposure to asbestos dust have been raised since at least the 1930s, but became heightened in the 1960s in light of increasing evidence of an association between asbestos exposure and lung cancer and the discovery of mesothelioma as an asbestos-related disease. Concerns that J&J's talcum powder products might be contaminated with asbestos first arose in the early 1970s.

In 1971, the head of New York City's Environmental Protection Administration, Jerome Kretchmer, asked Dr. Arthur Langer of Mt. Sinai Hospital to test various commercially available talc-based products for asbestos. Dr. Langer thereafter reported preliminary results indicating that samples from two undisclosed brands may have contained asbestos, prompting a press conference in June 1971 in which Mr. Kretchmer broadly asserted that "common talcum powder may contain potentially harmful quantities of asbestos particles" and that tests on two brands "revealed asbestos content ranging from 5 to 25 percent" and called for a federal investigation.[36]

This precipitated an approximately five-year period of public inquiry and investigation. During that period, regulators, industry representatives, and scientific experts debated the testing methods most appropriate to accurately detect the potential of asbestos in talc, and there were inconsistent, and often erroneous, reports concerning asbestos contamination of talc. Throughout that time, those reports and the asbestos-talcum powder controversy were widely publicized,

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No. MID-2912-17-AS) at 147:23-148:2 ("You can't take pieces of the non-asbestos rock and break it up and then call it asbestos.").

[36] Lawrence, S., "Talc Mnfr. Chafes at Warning", New York Post (7/30/1971), JNJ 000314584. In response to this claim, J&J publicly stated in 1971 that "[o]ur 50 years of research knowledge in this area indicates there is no asbestos in the powder made by Johnson and Johnson." 6/29/1971 Statement issued to New York Daily News and New York Post, JNJMX68_000015777.

including in outlets such as the *New York Times*[37] and the *Wall Street Journal*.[38]

On July 8, 1971, J&J met with the FDA concerning the safety of talc.[39] J&J provided the FDA with two reports from the Colorado School of Mines Research Institute ("CSM"), which included x-ray analyses of its Vermont and Italian talc products and a sample of lot "344L"—the same lot as the sample that Dr. Langer tested—as well as an additional report from a professor at Dartmouth concerning methods for analyzing talc.[40] A doctor from J&J then visited Dr. Langer in his lab, where Dr. Langer demonstrated the technique he had used to analyze talc.[41] He analyzed a sample of Johnson's Baby Powder using light microscopy, and claimed to have found some "non-plate particles," which "could be amphiboles[,] other asbestos forms, or fibrous talc."[42] The J&J doctor disagreed, believing that they were talc plate fragments.[43] Dr. Langer stated that using that technique he had estimated that Johnson's Baby Powder contained 5%

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37 3/10/1976 The New York Times, *Asbestos Found In Ten Powders*. JNJ 000004381.

38 3/12/1973 Letter from Dr. Lewin to the Editor of the Wall Street Journal re: Asbestos Report, JNJ 000244743.

39 7/8/1971 Memorandum of Meeting between J&J and FDA re: Asbestos Particles in Talc, JNJTALC000411518-521.

40 *Id.*; 6/24/1971 CSMRI Report on Particle Size and Shape Distribution of Grantham, Italian and Vermont Talc Final Products, JNJ 000234805-812; 7/7/1971 Letter from M. Pattengill to W. Ashton re results of re x-ray analyses on Vermont talc samples, JNJTALC000291175-178. The CSM reports initially identified trace amounts of "tremolite-actinolite" and "nontalc needles" in certain of the samples. These reports were disclosed to the FDA, but CSM subsequently clarified that further testing had shown no asbestos or "asbestos-type minerals," and that the "nontalc" needles were in fact most likely rolled up plates of talc. CSM concluded that "we cannot positively identify any asbestos-type minerals in the Vermont final product samples." 8/6/1971 Letter from Colorado School of Mines to Bill Ashton Re Vermont Talc Samples, JNJTALC000091746. The Dartmouth report similarly concluded that "[n]o amphibole, garnet or asbestos impurities were observed . . . ." 6/28/1971 Dartmouth University Letter to R.N. Miller (Windsor) re X-ray and Optical Examination of Talc Products, JNJTALC000292635-640 at 5.

41 7/9/1971 Internal J&J Memorandum Summarizing J&J's July 9, 1971 Meeting with Dr. Langer, JNJTALC000298751-756.

42 *Id.* at 3-4.

43 *Id.*

"fibrotic" particles, "of which some could be 'asbestos[.]'"[44] Using electron microscopy, Dr. Langer claimed to identify certain fibers as chrysotile by their appearance.[45]

In response to a June 1971 letter from Mr. Kretchmer, and due to "differing reports" concerning potential contamination of talc with asbestos, the FDA began its own investigation.[46] On August 3, 1971, the FDA hosted a symposium titled "Asbestos and Talc," attended by over 40 scientists, physicians, and consumers.[47] Participants discussed a variety of testing instruments available to test talc for the presence of asbestos, including x-ray diffraction ("XRD"), Polarized Light Microscopy ("PLM"), and Transmission Electron Microscopy ("TEM") with selected area electron diffraction ("SAED").[48] The FDA proposed to collect and synthesize detailed procedures on analytical methodology for comment.[49] The FDA also commissioned Dr. Seymour Lewin of New York University—an internationally recognized expert on mineralogical chemistry and one of the participants in the symposium—to test various talc products for asbestos and study what testing protocols would be most effective.[50] Initially, Dr. Lewin was asked to test 100 samples of commercially available product, although that mandate was ultimately expanded to 195.[51]

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44 *Id.* at 4.

45 *Id.* at 5.

46 8/3/1971 FDA Memorandum Regarding the Aug. 3, 1971 Symposium About Asbestos and Talc, JNJ 000086545-551.

47 *Id.*

48 *Id.*

49 *Id.*

50 *Id.*; 7/31/1973 Internal FDA Memorandum from Alfred Weissler to Robert M. Schaffner re Summary and Comments on Prof. Lewin's Analytical Results for Asbestos in Talc [Recently identified on publicly filed exhibit list in *Prudencio* as DX-17068] at 1.

51 7/31/1973 Internal FDA Memorandum from Alfred Weissler to Robert M. Schaffner re Summary and Comments on Prof. Lewin's Analytical Results for Asbestos in Talc [Recently identified on publicly filed exhibit list in *Prudencio* as DX-17068] at 1.

Meanwhile, J&J provided samples of its Vermont talc—including from the same 344L lot tested by Dr. Langer—to various outside experts, including CSM, Dr. Fred Pooley of the Cardiff University Department of Mineral Exploration, and McCrone Associates, Inc. ("McCrone"), which was at the time regarded as one of the leading experts in particulate testing.[52] None were able to replicate Dr. Langer's finding of asbestos.[53]

In June 1972, a *New York Times* article reported that Dr. Langer had admitted that his preliminary findings were incorrect.[54] He stated that the New York City EPA's 1971 claim that he had found "from 5 to 25 per cent asbestos fibers" in talc from J&J and another company was "absolutely untrue."[55] He clarified that further analysis found only "trace amounts,"[56] and that what "he thought to be mineral fibers turned out in later research to be talc itself."[57] A spokesperson for the FDA was also quoted as saying that tests of Johnson's Baby Powder in March 1972 had shown "no detectable content of asbestos."[58]

In August 1972, Dr. Lewin provided preliminary results from his testing of the first 100 samples to the FDA.[59] Although samples of Johnson's Baby Powder and another product—J&J's Medicated Powder—were found to be free from asbestos, Dr. Lewin claimed to have found up to

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52 8/10/1971 Fred Pooley's Report Analyzing 10 Talc Samples, JNJ 000274547-556; 8/19/1971 McCrone Report Analyzing the Vermont #344-L Sample, JNJ 000260792-799; 8/6/1971 Letter from Colorado School of Mines to Bill Ashton Re Vermont Talc Samples, JNJTALC000091746.

53 *Id*.

54 Lichtenstein, G., *Talc Warning is Labeled False*, N.Y. Times (6/17/1972), JNJ 000244787.

55 *Id*.

56 On November 10, 1971, responding to an August 9 inquiry from J&J, Dr. Langer informed J&J that he had found "trace amounts"—less than 0.01%—of chrysotile in a talc sample of lot 344L Vermont talc. 11/10/1971 Letter from Dr. Langer to Hildick-Smith re Tenovus Samples, JNJTALC000298765-767 at 3.

57 Lichtenstein, G., *Talc Warning is Labeled False*, N.Y. Times (6/17/1972), JNJ 000244787.

58 *Id.*

59 8/3/1972 Letter from Dr. Lewin to Dr. Weissler [Recently identified on publicly filed exhibit list in *Prudencio* as DX-20118].

5% chrysotile in a sample of J&J's Shower to Shower product, which was produced from Italian talc, by x-ray diffraction.[60] J&J's own testing had found no chrysotile in Italian talc, its Shower to Shower product, or the sample studied by Dr. Lewin.[61]

In connection with a presentation before the FDA in September 1972, J&J provided the FDA with the reports it had received from Dr. Pooley, Atomic Energy Research Establishment at Harwell, the Mining Institute of Torino, Italy, Massachusetts Institute of Technology, Princeton University, McCrone, CSM, Carnegie-Mellon University, and Sperry Rand concerning Shower to Shower and the Italian talc mine from which the talc in that product was sourced.[62] The data in those reports firmly established that (i) there was no chrysotile asbestos in the Italian mine; (ii) the powder made from Italian talc has been shown to be free from chrysotile; (iii) "investigations by all available methods" failed to establish the presence of any chrysotile in Shower to Shower; and, ultimately (iv) that "Lewin's finding [was] wrong and [had] no basis in fact."[63]

Around the time of the September 1972 FDA meeting, Dr. Lewin reported updated preliminary results from his expanded testing of 195 samples.[64] In addition to his prior findings with regards to Shower to Shower, Dr. Lewin claimed to have found 2-3% chrysotile in two samples of Johnson's Baby Powder produced from Vermont talc (samples from lot "108T" and lot "109T").[65] The McCrone laboratory later determined that particles identified as chrysotile by

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60 *Id.*

61 10/17/1972 Letter from W. Nashed to R. Schaffner re Shower-To-Shower Brand Body Powder with attachment, JNJTALC000300260-496.

62 *Id.*

63 *Id.* at 2.

64 9/26/1972 Findings on Johnson & Johnson Products from a Report by Dr. S. Lewin, JNJ 000232996-3002.

65 *Id.*

Dr. Lewin during the meeting were, in fact, calcium silicate.[66]

J&J submitted retained samples of talc from the same lots—108T and 109T—to many of the same external experts that had tested its Shower to Shower product, including McCrone, CSM, Dr. Pooley, and Professor Brown of Princeton University.[67] J&J also conducted its own testing.[68] On November 29, 1972, J&J submitted the results of those tests to the FDA, indicating that they "clearly show that the lots in question . . . contain no chrysotile asbestos."[69] Other internal and external investigators engaged by the FDA reported results that were also inconsistent with Dr. Lewin's findings.[70]

In a letter to the editor of the *Wall Street Journal* in March 1973, Dr. Lewin wrote that prior reports that he had found 2% to 3% chrysotile in J&J talc were erroneous.[71] He clarified that there was no asbestos in 9 of the 11 samples tested, and that the results for the other two samples had been "inconclusive[,]" owing to the limitations inherent in his testing methods.[72] His results, he stated, were "not seriously at variance with those reported by investigators retained by [J&J]."[73] In July 1973, Dr. Lewin made a final report to the FDA.[74] In that report, he noted that the chrysotile he had found in some commercial talc is "different in significant

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66 10/9/1972 Memo from Walter McCrone to Ian Stewart re: Visit with Dr. Seymour Lewin, 10/3/1972, JNJTALC000437173-179.

67 11/29/1972 Submission by Dr. Nashed to FDA re: Johnson's Baby Powder, JNJ 000317600-658.

68 *Id.* at 65.

69 *Id.*

70 *See, e.g.*, 1/7/1976 Yates (FDA) memo to Eiermann (FDA) re: Tabulated results of DCST's Analyses for Asbestos Minerals [Recently identified on publicly filed exhibit list in *Prudencio* as DX-17113].

71 3/12/1973 Letter from Lewin to the Editor of the Wall Street Journal re Asbestos Report, JNJ 000244743.

72 *Id.*

73 *Id.*

74 7/10/1973 Memo from Prof. Seymour Lewin (NYU) to George Thompson (FDA) Final Report: Determination of Asbestos Contents of Commercial Talcum Powders [Recently identified on publicly filed exhibit list in *Prudencio* as DX-17066].

respects" from that found in nature, and that several "complicat[ing]" factors made identification and quantification of chrysotile difficult.[75] The report did not list any amount of chrysotile detected in J&J products, but also did not state "n.d." or "none detected."[76] Rather, Dr. Lewin reported a "?" as to the chrysotile content of each sample for which he had previously reported a finding of chrysotile.[77]

An FDA memorandum summarizing and commenting on Dr. Lewin's report noted significant inconsistencies between Dr. Lewin's findings and those of other laboratories consulted by the FDA (as well as those of J&J and its consultants), which the FDA found may have been caused by Dr. Lewin's expansive definition of what should be considered "chrysotile."[78] Later in 1973, again citing "poor correlation between Dr. Lewin's results and the findings of the other investigators[,]" the FDA instituted "an intensive research project to develop one or several methods of sufficient sensitivity and reliability which will permit the determination of asbestos in talc-containing products with the necessary degree of accuracy and at concentrations at which this contaminant presents the health hazard."[79]

By early January 1976, the Division of Cosmetics Technology, a former department at the FDA, had internally retested all of the samples previously tested by Dr. Lewin using either differential thermal analysis ("DTA") or optical microscopy.[80] It found no chrysotile in J&J's

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75 *Id.* at 2.

76 *Id.*

77 *Id.* at tbl. 1.

78 7/31/1973 Internal FDA Memorandum from Alfred Weissler to Robert M. Schaffner re Summary and Comments on Prof. Lewin's Analytical Results for Asbestos in Talc [Recently identified on publicly filed exhibit list in *Prudencio* as DX-17068].

79 10/1/1973 Memo from Heinz J. Eiermann, "Summary and Comments on Analyses for Asbestos in Cosmetic Talc Products," JNJ 000247504.

80 1/7/1976 Yates (FDA) memo to Eiermann (FDA) re: Tabulated results of DCST's Analyses for Asbestos Minerals [Recently identified on publicly filed exhibit list in *Prudencio* as DX-17113].

talcum powder products.[81] Later that same year, Dr. Langer and others from the Mt. Sinai Environmental Sciences Laboratory published a study of 21 talc-based cosmetic products—including two Johnson's Baby Powder samples, one manufactured in the U.S. and one in the U.K., and one Johnson's Medicated Powder—that had been conducted as part of a study of effective techniques for measuring the presence of asbestos in talc.[82] That study used several methods to test the products, including TEM, and found no asbestos in J&J's talcum powder products.[83] A press release from Mt. Sinai at the time stated that "the most commonly used baby talc[,]" which was Johnson's Baby Powder, "has been consistently free of asbestos[,]" and that it was "the opinion of Mount Sinai's Department of Pediatrics that baby talc is a useful and safe product."[84]

D. Since the 1980s, Studies Have Failed to Demonstrate Support for Claims that Talc Causes Ovarian Cancer.

The first known study investigating a potential association between talc powder use in the female genital area and ovarian cancer was conducted by Dr. Daniel W. Cramer, who published a study in the July 15, 1982 issue of the journal *Cancer* (the "Cramer Study").[85] The Cramer Study was a "case-control" study, a type of observational study that compares persons who have

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81 *Id.* In 1980, in a book titled "The Asbestos Particle Atlas," prepared as part of a project with the U.S. EPA concerning asbestos testing using microscopy, Dr. McCrone wrote of Dr. Lewin's work that to "the credit of the FDA, they did not push the panic button but did alert the cosmetics industry and retain[ed] additional experts to check these alarming results" and it "finally became apparent that [Dr. Lewin's] original report was grossly wrong." McCrone, W., THE ASBESTOS PARTICLE ATLAS (1980) at 3. Dr. McCrone also criticized a 1976 report from Dr. Langer at Mt. Sinai, which claimed to find asbestos in talc products (but not J&J's talcum powder products), for counting non-chrysotile, "nonfibrous" amphiboles as asbestos based on aspect ratio, a decision Dr. McCrone called "silly[.]" *Id.* at 4.

82 Rohl, A. N., et al., "Consumer Talcums and Powders: Mineral and Chemical Characterization," J. OF TOXICOL. AND ENV'T HEALTH, 2:255-284 (1976) ("Rohl 1976").

83 *Id.*

84 3/23/1976 Press Release from Dr. Thomas Chalmers, President of Mt. Sinai Medical Center, JNJ 000026953-955.

85 Daniel W. Cramer et al., *Ovarian Cancer and Talc: A Case-Control Study*, 50 CANCER 372 (1982).

experienced a particular outcome or disease (cases)—in this case ovarian cancer—with persons who have not (controls), looking back (retrospectively) and attempting to measure in each group exposures of interest and assess potential risk factors. The study involved 430 women: 215 women who were diagnosed with ovarian cancer in and around Boston between November 1978 and September 1981 and 215 women matched by age, race, and residence were interviewed to determine, *inter alia*, medical and family history, environmental exposures, and potential or definite past talc exposure by way of contraceptive practices, operations, or perineal hygiene.[86]

Because they require less time to conduct than prospective (or forward looking) observational studies, as well as allowing for analysis of multiple risk factors, case control studies often are used to generate initial hypotheses.[87] But while prospective studies may also have certain limitations, case-control studies have certain unique limitations when used to investigate hypotheses. For example, exposure data may be impaired by recall bias—the tendency of people already diagnosed with a disease to more readily recall exposure to an agent.[88] The effect of a particular risk factor may also be distorted by "confounding," which

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86 *Id.* at 372-73.

87 *See* S. Lewallen & P. Courtright, *Epidemiology in Practice: Case-Control Studies*, 11 CMT'Y EYE HEALTH 57, 57 (1998) ("Lewallen & Courtright 1998") (Case-control studies "are comparatively quick, inexpensive, and easy. . . . Because of their efficiency, they may also be ideal for preliminary investigation of a suspected risk factor for a common condition; conclusions may be used to justify a more costly and time-consuming longitudinal study later."); Michael D. Green et al., *Reference Guide on Epidemiology*, in REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 549, 560 (3rd ed. 2011) ("Green 2011") ("An advantage of the case-control study is that it usually can be completed in less time and with less expense than a cohort study.").

88 *See* Lewallen & Courtright 1998 at 58; Katie M. O'Brien et al., *Association of Powder Use in the Genital Area With Risk of Ovarian Cancer*, 323 J. AM. MED. ASS'N 49, 50 (2020) ("O'Brien 2020") ("Case-control studies have reported positive associations . . . However, these findings may be affected by recall bias, and a recent surge in talc-related lawsuits and media coverage has increased this possibility. Thus, it is crucial to evaluate the talc–ovarian cancer association using prospective data."); Berge et al., *Genital Use of Talc and Risk of Ovarian Cancer: A Meta-Analysis*, 27(3) EUR J. CANCER PREVENTION 248, 253 (2018) ("Berge 2018") ("The fact that the association between genital talc use and risk of ovarian cancer is present in case-control, but not in cohort studies, can be attributed to bias in the former type of studies."); Langseth, et al., *Perineal Use of Talc and Risk of Ovarian Cancer*, 62 J. EPIDEMIOLOGY & CMT'Y HEALTH 358, 358 (2008) ("Langseth 2008") ("Another source of recall bias could result from the fact that women with the cancer

occurs when an exposure and disease are actually both strongly associated with other factors that influence the outcome.[89]

According to the Cramer Study, the "only significant finding was an association between ovarian cancer and hygienic practices involving the use of talc on the perineum."[90] The study noted, however, that the reason for the association was unclear and called for further investigation into the ways talc might interact with known risk factors, as well as additional epidemiological study with "[m]ore precise details on the exact nature and frequency of the exposure . . . ."[91] It is important to note that "association" does not mean "causation." "[W]hether an association is causal requires an understanding of the strengths and weaknesses of the study's design and implementation, as well as a judgment about how the study findings fit with other scientific knowledge."[92]

Nonetheless, J&J/Old JJCI took the assertions made in the Cramer Study seriously, but believed that there were critical flaws in the data used to support Dr. Cramer's conclusion that there may be an association between talc and ovarian cancer. Two representatives—including Old JJCI's Medical Director—met with Dr. Cramer in Boston shortly after publication and,

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tend to remember or over report their use of body powder. The influence of this type of recall bias cannot be ruled out.").

89 Lewallen & Courtright 1998 at 58.

90 Cramer Study at 375. About 43% of the cases indicated in their interviews that they regularly used talc either as powder on their perineum or on sanitary napkins (or both) compared to about 28% of the controls, resulting in an adjusted relative risk of 1.92 with 95% confidence limits of 1.27-2.89 compared to subjects who had neither exposure. *Id.* at 374. The study further stated "[i]t is especially notable that women who regularly had both dusted their perineum with talc and had used it on sanitary napkins had more than a three-fold increase in risk compared to women with neither exposure. Several potential biases must be considered in interpreting this association." *Id.* at 375.

91 *Id.* at 376.

92 Green 2011 at 553.

among other things, raised their concerns with Dr. Cramer's study design.[93] Dr. Cramer admitted flaws in his study, yet stood by the conclusion.[94] J&J/Old JJCI presented a critique of the Cramer Study at a 1982 meeting of the Cosmetics, Toiletries and Fragrance Association's ("CTFA") Pharmacology & Toxicology Committee, which Committee thereafter decided to engage a consulting epidemiologist to review the study and form a task force to investigate further.[95] The Cramer Study and J&J's/Old JJCI's response thereto received media attention, including an August 12, 1982 *New York Times* article.[96]

In the close to four decades between the Cramer Study in 1982 and today, at least 34 case-control studies, including Cramer (1982), have been published looking at a potential association between perineal talc use and ovarian cancer. 27 such studies were population-based, meaning the cases were selected from a defined population, such as a fixed geographic area, and the controls were healthy women randomly selected from the same population. Seven were hospital-based, meaning the controls were selected from among women referred to the same medical facility as the cases, but for reasons other than ovarian cancer, and included 4,124 total participants. In all, 17 of the 27 population-based studies reported some association, but with risk ratios ranging only from 1.2 to 1.9. Such a relative risk is considered weak by

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93 Among other issues, Old JJCI raised the following with Dr. Cramer: (i) Dr. Cramer's questionnaire only asked about current usage of talc (not historical usage); and (ii) the discrepancy between the low (28%) use of talc in the perineal area by Dr. Cramer's control group and the results of market research, which showed close to 70% of the 2,214 females surveyed indicated that they had used talc, and thus reflected an issue with the representativeness of Cramer's control group. *See* 8/12/1982 Memo from Steven Phillips re "Talc and Ovarian Cancer – Site Visit with Dr. Cramer," JNJ 000029640 – 41.

94 *Id.*

95 *See* 8/20/1982 Memo from George Lee re "CTFA Pharmacology & Toxicology Committee – Ovarian Cancer and Talc," JNJ 000029639.

96 *See Talcum Company Calls Study on Cancer Link Inconclusive*, The New York Times (Aug. 12, 1982), *available at* https://www.nytimes.com/1982/08/12/business/talcum-company-calls-study-on-cancer-link-inconclusive.html.

epidemiological standards.[97] Significantly, none of the hospital-based studies, which have a reduced risk of recall bias, reported a statistically significant association.

While the case-control studies are inconsistent as to the finding of a statistically significant positive association, not one of the authors of the case-control studies that reported an "association" took the position that its findings establish causation.

In addition to the case-control studies, there have been four published cohort studies examining whether there is an association between talc exposure and ovarian cancer. Unlike case-control studies, cohort studies are prospective, in that they identify a group of healthy subjects and follow them forward in time to see how many develop the disease being studied. In total, the cohort studies followed more than 200,000 women, and **none of the studies reported an overall association between exposure to talc and ovarian cancer**.

The first published cohort study ("Gertig 2000")[98] was based on data from the Nurses' Health Study ("Nurse's Study" or "NHS"), a U.S. government-funded study that began in 1976 and followed more than 121,700 female registered nurses ages 30-55 to identify risk factors for major chronic diseases. Every two years, the women answered questions concerning their

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97 Wynder, et al., *Weak Associations in Epidemiology and Their Interpretation*, 11 PREVENTATIVE MED. 464, 465 (1982) ("Wynder 1982") ("[T]he term 'weak' refers to relative risks between 1.0 and 2.0."); Berge 2018 at 248 ("weak" association); Nat'l Cancer Inst., Ovarian, Fallopian Tube, and Primary Peritoneal Cancer Prevention (PDQ®)–Health Professional Version, *available at* https://www.cancer.gov/types/ovarian/hp/ovarian-prevention-pdq (last updated July 8, 2021) ("NCI 2021 PDQ") (NCI concluding that "[t]he weight of evidence ***does not support an association*** between perineal talc exposure and an increased risk of ovarian cancer") (emphasis added); 4/1/2014 FDA's 2014 denial of Citizen's Petition requesting warning on talcum powder products and related correspondence [Recently identified on publicly filed exhibit list in *Prudencio* at DX-17456] at 4 (discounting the case-control studies that reported a "small positive association[]" because they have confidence intervals that "are often close to 1.0"); IARC 2010 Monograph at 412 (referring to the association as "modest"); Gossett & del Carmen, *Use of Powder in the Genital Area and Ovarian Cancer Risk*, 323(1) JAMA 29, 29 (2020) ("Gossett & del Carmen 2020") (describing several case-control studies on the alleged link between ovarian cancer and perineal talc use as having "relatively small effect sizes—odds ratios (ORs) of 1.24 to 1.6.").

98 Gertig et al., *Prospective Study of Talc Use and Ovarian Cancer*, 92 J. NAT'L CANCER INST. 249 (2000).

medical history and risk factors for a number of diseases. In 1982, they were asked about the frequency of their exposure to perineal talc. The responses to those questions were used to identify a cohort of 78,630 women analyzed in the Gertig 2000 study. The study reported "no overall association with ever talc use and epithelial ovarian cancer" and "no increase in risk of ovarian cancer with increasing frequency of use" (*i.e.*, no "dose response").[99] When the data was stratified by histologic type, "[t]here was a modest elevation in risk for ever talc use and invasive serous ovarian cancer" (although not all serous cancers),[100] but the authors concluded that the "results provide little support for any substantial association between perineal talc use and ovarian cancer risk overall[.]"[101]

The second published cohort study ("Gates 2010")[102] reported on the Nurse's Study after ten additional years of follow-up. This study was designed to specifically evaluate the risk factors for various histologic types of epithelial ovarian cancer.[103] Like the Gertig 2000 study, Gates 2010 found no overall association between talc use and ovarian cancer.[104] Moreover, Gates 2010 found no elevated risk specific to invasive serous ovarian cancer,[105] meaning that the potential association previously detected was no longer seen after an additional decade of research and the diagnosis of an additional 490 cases.

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99 *Id.* at 249.

100 *Id.*

101 *Id.*

102 Gates et al., *Risk Factors for Epithelial Ovarian Cancer by Histologic Subtype*, 171 AM. J. EPIDEMIOLOGY 45 (2010).

103 *Id.* at 45.

104 *Id.* at 50 tbl. 4.

105 *Id.*

The third cohort study ("Houghton 2014")[106] used data from the Women's Health Initiative ("WHI") Study, which was established by the U.S. National Institutes of Health in 1991 to study the health of postmenopausal women. The portion of the study looking at talc use followed 61,576 women, 52.6% of whom said they had used talcum powder in the perineal area (some for decades), from 1993 and 2012.[107] The study found no increased risk from "any" genital use of talc, from use for 10 or more years or 20 or more years, or from use on sanitary napkins or diaphragms, and ultimately concluded that "perineal powder use does not appear to influence ovarian cancer risk."[108]

A fourth cohort study ("Gonzalez 2016")[109] looked at data from the "Sister Study," a study that enrolled 50,884 women in the U.S. and Puerto Rico who had a sister diagnosed with breast cancer, and followed 41,654 of those women for a median 6.5 years. Gonzalez 2016 found no association between the use of talc and ovarian cancer.[110] Gonzalez 2016 actually found an inverse association between talc and ovarian cancer, which would suggest that talc prevented such cancer, however that association was not statistically significant.[111]

Finally, a number of "meta-analyses" and "pooled studies"—which use statistical methods to combine, assess, and summarize results and data from multiple of the above-

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106 Houghton et al., *Perineal Powder Use and Risk of Ovarian Cancer*, 106(9) J. NAT'L CANCER INST. 1 (2014).

107 *Id.* at 1.

108 *Id.*

109 Gonzalez et al., *Douching, Talc Use, and Risk of Ovarian Cancer*, 27(6) EPIDEMIOLOGY 797 (2016).

110 *Id.* at 797, 802.

111 *Id.* at 800. Gonzalez 2016 separately found an association between douching and ovarian cancer, and a correlation between douching and talc exposure, suggesting that douching could be a confounding factor in studies of talc and ovarian cancer risk. *Id.*

described studies—have been conducted. Those analyses have generally reported a relative risk of approximately 1.3 driven largely, if not exclusively, by the case-control studies noted above.

For instance, two recent studies that stratified their results by study type, Berge 2018 and ("Penninkilampi 2018"),[112] both found a statistically significant increase in risk suggested by the case-control studies (Berge 2018 classified that association as "weak"), but no statistically significant increased risk suggested by the cohort studies.[113] Berge 2018 noted that "studies reported during the last three decades have not been consistent" and that "[i]t remains unclear whether a statistical association exists, and, if so, whether it can be interpreted as reflecting some form of bias or a causal relationship."[114] Further, although a "small but statistically significant association" was identified, "the heterogeneity of results between case-control and cohort studies," and the weak trend in relative risk with "duration and frequency of genital talc use" "do not support a causal interpretation of the association."[115] The results of the review in Penninkilampi 2018 "indicate[d] that perineal talc use is associated with a 24%-39% increased risk of ovarian cancer."[116] The authors noted that the evidence was "suggestive"—though not dispositive—"of a causal association," despite the fact that "the results of case-control studies are

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112 Penninkilampi et al., *Perineal Talc Use and Ovarian Cancer: A Systematic Review and Meta-Analysis*, 29 EPIDEMIOLOGY 41 (2018).

113 Berge 2018 at 251; Penninkilampi 2018 at 44.

114 Berge 2018 at 249. In addition to showing up only in "case-control studies," Berge 2018 noted that the "small but statistically significant association" was limited to the "serous histologic type" of ovarian cancer. *Id*. at 256.

115 Berge 2018 at 248, 256. Penninkilampi 2018, discussing the talc-litigation facing J&J/Old JJCI, noted that "[t]he evidence for the association between perineal talc use and ovarian cancer is based on the body of knowledge from observational studies, and most of these have been retrospective case-control studies prone to recall bias. Hence, while perineal talc use has not been shown to be safe, in a similar regard, a certain causal link between talc use and ovarian cancer has not yet been established." Penninkilampi 2018 at 42.

116 Penninkilampi 2018 at 47.

prone to recall bias, especially with intense media attention following the commencement of litigation in 2014."[117]

Most recently, a January 2020 U.S. government-funded pooled analysis published in the Journal of the American Medical Association (O'Brien 2020) reviewed the data on over 250,000 women pooled from the cohort studies—NHS (as well as a follow-up to the original NHS), the Sister Study, and the WHI. The study was led by an epidemiologist from the National Institute of Environmental Health Sciences, and was specific to the association between perineal talc use and ovarian cancer. The authors reported that "there was not a statistically significant association between use of powder in the genital area and incident ovarian cancer" and, moreover, there was no evidence of a strong ovarian cancer risk when researchers looked at women who had used talc for longer periods, or more frequently.[118]

E. Decades of Examination by Regulatory and Health Authorities Demonstrate the Safety of Johnson's Baby Powder.

Following claims in the 1970s and 1980s that talc body products purportedly contained asbestos and that talc could increase the risk of cancer, the FDA and other health authorities have repeatedly examined and weighed in on the safety of talc products.

In July 1986, the FDA responded to a Citizen Petition concerning the safety of talc submitted by a graduate student of Marine Environmental Sciences named Phillippe Douillet (the "Douillet Petition").[119] Citing studies from the 1970s that purportedly detected asbestos in

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117 *Id.*

118 O'Brien 2020 at 49.

119 7/11/1986 Letter from J.W. Swanson, Acting Associate Commissioner for Regulatory Affairs, U.S. Food and Drug Administration, to P. Douillet with enclosures re: Petition Requesting that Cosmetic Talc be Labeled with and Asbestos Warning Statement, and related correspondence [Recently identified on publicly filed exhibit list in *Prudencio* as DX-17214].

commercially available cosmetic talc products and the known health risks posed by asbestos, the Douillet Petition requested that the FDA mandate that cosmetic talc product labels include information concerning asbestos content, as well as a warning of the hazardous health effects of asbestos.[120]

In its response to the Douillet Petition, the FDA explained that the agency had also been concerned about potential asbestos contamination in the early 1970s, after it "received several reports about such contamination."[121] At that time, however, the "analytical procedures" for testing talc for asbestos "were not fully developed" and "most of the analytical work was conducted without scientific agreement as to which methods" for such testing were appropriate.[122] Therefore, FDA considered "all analytical results" during that period to be of "questionable reliability."[123] The FDA's response enclosed a National Bureau of Standards Special Publication titled "Misidentification of Asbestos in Talc[,]" which raised "many questions" about the testing that had been conducted in the early 1970s.[124] The agency also noted that the asbestos paper cited in the Douillet Petition specifically was plagued by "significant errors[,]" and had been rebutted by a report from the Chief Mineralogist at the Colorado School of Mines Research Institute.[125]

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120 11/8/1983 Letter from Philippe Douillet to U.S. Food and Drug Administration regarding Citizen's Petition and related correspondence [Recently identified on publicly filed exhibit list in *Prudencio* as DX-17185].

121 7/11/1986 Letter from J.W. Swanson, Acting Associate Commissioner for Regulatory Affairs, U.S. Food and Drug Administration, to P. Douillet with enclosures re: Petition Requesting that Cosmetic Talc be Labeled with and Asbestos Warning Statement, and related correspondence [Recently identified on publicly filed exhibit list in *Prudencio* as DX-17214] at 3.

122 *Id.*

123 *Id.*

124 *Id.*

125 *Id.* at 4.

According to the FDA's response to the Douillet Petition, the agency, in light of inconsistent reports and uncertainty surrounding talc testing in the early 1970s, had decided to release to the public the testing reports that the FDA had received, and to work with the cosmetics industry to "develop[] acceptable analytical procedures."[126] In 1976, that effort culminated in the industry's adoption of the CTFA J4-1 Method, which required that cosmetic talc be free of detectable asbestos by a combination of x-ray diffraction and, if necessary, polarized light microscopy.[127] The FDA had also, "in the latter portion of the 1970s[,]" undertaken its own surveillance testing of cosmetic talc, which, according to its own risk assessment, showed that the "risk from a worst-case estimate of exposure to asbestos from cosmetic talc would be less than the risk from environmental background levels of exposure . . . over a lifetime."[128] Consequently, the FDA determined that there was no basis to conclude that there was a health hazard attributable to asbestos in talc, and that there was no basis to require a warning label.[129]

In connection with the FDA's evaluation of the Douillet Petition, the Department of Health and Human Services' Quantitative Risk Assessment Committee performed an assessment of the risk of lung cancer, mesothelioma, and ovarian cancer to infants from potential asbestos contamination in talc. The Committee's report, dated June 6, 1985, referenced the "general

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126 *Id.*

127 10/7/1976 CTFA Method J 4-1, Testing Monograph; Asbestiform Amphibole Minerals in Cosmetic Talc, Part I: X-ray Diffraction Method, Part II: Optical Microscopy and Dispersion-Staining Method, JNJ 000405219-228.

128 7/11/1986 Letter from J.W. Swanson, Acting Associate Commissioner for Regulatory Affairs, U.S. Food and Drug Administration, to P. Douillet with enclosures re: Petition Requesting that Cosmetic Talc be Labeled with and Asbestos Warning Statement, and related correspondence [Recently identified on publicly filed exhibit list in *Prudencio* as DX-17214] at 4.

129 *Id.*

consensus that current talc mines are virtually free of asbestos[,]" but assumed two-year exposure to talc contaminated with 0.1% asbestos.[130] The report concluded that "any hypothetical systemic added lifetime cancer risk . . . to humans due to asbestos fibers in talc (principally for babies subject to 2 years of talc dusting) appears to be less than 10-8 added lifetime risk and possibly several orders of magnitude lower risk still[.]"[131] In surveying the relevant literature relating to ovarian cancer, the report criticized the Cramer Study as "uncorrected for several likely biasing factors," and "strongly contradicted by another study showing a reduced relative risk as significant in the negative direction[.]"[132] The report concluded that "there appears to be no association between customary human talc use per se and ovarian cancer."[133]

In early 1994, the FDA, the International Society of Regulatory Toxicology & Pharmacology ("ISRTP") and the CTFA, co-sponsored a public conference titled "Talc: Consumer Uses and Health Perspectives."[134] A primary focus of the conference, which was attended by a number of experts, industry and consumer representatives, and regulatory specialists, was "the then-latest toxicological and epidemiological studies as they related to the safe uses of talc in cosmetic products."[135] Of "special interest" was a study, published the prior year by the National Toxicology Program ("NTP"),[136] on the effects of micronized talc exposure

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130 6/6/1985 Memo from Robert Brown, et al. (Quantitative Risk Assessment Committee) to W. Gary Flamm (Dir. Office Toxicology Sciences) re Asbestos in Talc, FDA00003626-3636 [Recently identified on publicly filed exhibit list in *Prudencio* as DX-17201] at 2.

131 *Id.* at 9.

132 *Id.* at 6.

133 *Id.* at 9.

134 1/31/ 1994 - FDA Workshop on Talc: Consumer Uses and Health Perspectives, JNJTALC000019209-588.

135 Fiume 2015 at 67S.

136 The NTP is an interagency program composed of, and supported by, three government agencies within the Department of Health and Human Services: the National Center for Toxicological Research of the FDA;

on rats and mice.[137] That study had found that there was some evidence of carcinogenic activity in male rats, based on increased incidences of tumors in the adrenal glands, and clear evidence in female rats based on increased incidence of tumors in the lungs and adrenal glands.[138] The study was publicly criticized for a number of reasons, including that the study had exposed the rats to such high levels of talc that the tumor formation observed was likely caused by "dust overload," and not talc specifically.[139] Experts also reviewed the epidemiological literature related to talc and ovarian cancer, as well as whether there was a basis to believe that talc applied to the perineal region could migrate to the ovaries. Ultimately, the workshop's panel concluded that the 1993 NTP study "cannot be considered as relevant predictors of human risk[,]" and that the "epidemiological data" concerning "the proposed association of talc exposure and ovarian cancer . . . are conflicting and remain equivocal" and inadequate to "raise concern at a level sufficient to warrant regulatory or public health measures[.]"[140]

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the National Institute of Environmental Health Sciences of the National Institutes of Health; and the National Institute for Occupational Safety and Health of the Centers for Disease Control and Prevention.

137 National Toxicology Program. Toxicology and carcinogenesis studies of talc (CAS No. 14807-96-6) in F344/N rats and B6C3F1 mice (Inhalation studies). NTP TR 421.NIH Publication No. 93-3152. 1993.

138 *Id*. There was no evidence of carcinogenic activity in male or female mice. *Id*. Notably, a follow-up study that looked at the ovaries of the rats found no evidence of talc in the ovaries and no exposure related lesions or tumors. Boorman, G., et al., *The Lack of an Ovarian Effect of Lifetime Talc Exposure in F344/N Rats and B6C3F1 Mice*, REGUL. TOXICOL. PHARMACOL., 21(2):242-3 (1995).

139 Fiume 2015 at 93S.

140 Carr CJ (Rapporteur), *Talc: consumer uses and health perspectives. Proceedings of a workshop. Bethesda, Maryland, January 31-February 1, 1994*. REGUL. TOXICOL. PHARMACOL. 1995;21(2):211-215. Talc was nominated in 2000 for review in the NTP's 10th "Report on Carcinogens" ("RoC"), a report mandated by Congress that identifies agents, substances, mixtures, or exposure circumstances (collectively referred to as "substances") that may pose a carcinogenic hazard to human health. The nomination was based in part on the results of the 1993 NTP study, and epidemiological evidence of an association with ovarian cancer. National Toxicology Program, Call for Public Comments on 8 Nominations, Proposed for Listing in or Delisting from the Report on Carcinogens, Tenth Edition. 66 Fed. Reg. 13334-13338 (March 5, 2001). Ultimately, the NTP deferred consideration in 2001 and then withdrew talc from the review in 2005 due to "considerable confusion over the mineral nature and consequences of exposure to talc, both containing asbestiform fibers and not containing asbestiform fibers," which makes it impossible "to reach definitive conclusions concerning the specific substances responsible for the range of adverse health outcomes reported." *Id*; National Toxicology Program, Report on Carcinogens; Status of Nominations to the 12th Report on Carcinogens (RoC): Request for Comments and Nominations of Scientific Experts. 70 Fed. Reg.

In November 1994, another Citizen Petition was sent to the FDA, this time by Samuel Epstein on behalf of the Cancer Prevention Coalition, a consumer advocacy group (the "First Epstein Petition").[141] The petition, citing the "large body of scientific evidence . . . on the toxicology and mineralogy of cosmetic talc products," claimed that "[t]alc is a carcinogen, with or without the presence of asbestos-like fibers" and that "frequent talcum powder application in the genital area increases a woman's risk of developing ovarian cancer."[142] It further requested that the FDA require warning labels on talcum powder products, such as "Talcum powder causes cancer in laboratory animals. Frequent talc application in the female genital area increases the risk of ovarian cancer."[143] The FDA responded on July 11, 1995 to say that "because of the limited availability of resources and other agency priorities[,]" the agency had been unable to reach a decision on the First Epstein Petition within the first 180 days after filing.[144]

In May 2008, Dr. Epstein submitted a second petition to FDA (the "Second Epstein Petition"), again requesting that the FDA immediately require that labels for cosmetic talcum powder products contain a prominent warning, such as "Frequent talc application in the female genital area is responsible for major risks of ovarian cancer."[145] The petition cited to public

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60548-60554 (Oct. 18, 2005). Today, talc is not included in the RoC, which was last issued in 2016. National Toxicology Program, Substances Listed in the Fourteenth Report on Carcinogens, Report on Carcinogens, Fourteenth Edition (Nov. 3, 2016), *available at* https://ntp.niehs.nih.gov/ntp/roc/content/listed_substances_508.pdf.

141 11/17/1994 Letter from Jill Cashen, Research Associate, Cancer Prevention Coalition Petition to Comm. Kessler, FDA, Enclosing Citizen Petition Seeking Carcinogenic Labeling on all Cosmetic Talc Products [Recently identified on publicly filed exhibit list in *Prudencio* at DX-17414].

142 *Id.* at 3-4.

143 *Id.* at 2.

144 7/11/1995 Letter from John Bailey, Act. Dir. Office Cosmetics and Colors, FDA to Jill Cashen, Cancer Prevention Coalition, Docket No. 94P-0420 [Recently identified on publicly filed exhibit list in *Prudencio* at DX-17398].

145 Epstein SS. Petition Seeking a Cancer Warning on Cosmetic Talc Products (May 13, 2008), *available at* https://www.reuters.com/investigates/special-report/assets/usa-health-fda-talc/epstein-2nd-petition.pdf.

statements and studies that had been conducted since the First Epstein Petition, and that, according to the petition, "confirm[ed]" a "causal relation between genital application of talc and ovarian cancer[.]"[146]

In 2009 and 2010, while evaluating the Epstein petitions, the FDA commissioned a survey of commercially available cosmetic talcs and talc-containing products, testing samples of talc collected from various suppliers as well as products purchased in stores in Washington, D.C.[147] The FDA tested both the Chinese talc used in Old JJCI's talcum powder products, as well as off-the-shelf samples of Old JJCI's talcum powder products.[148] The survey "found no asbestos fibers or structures in any of the samples of cosmetic-grade raw material talc or cosmetic products containing talc."[149]

In 2010, the World Health Organization's International Agency for Research on Cancer ("IARC") Working Group published its Monographs on the Evaluation of Carcinogenic Risks to Humans: Carbon Black, Titanium Dioxide, and Talc, reporting on its review of the scientific literature on talc to date. IARC concluded that the evidence was "inadequate" to assess whether inhaled talc caused cancer, and thus that "inhaled talc" was not classifiable as to its carcinogenicity to humans, but found that certain case-control studies showed a "modest" increase in risk of ovarian cancer from perineal use.[150] Although the report observed that "the impact of bias and potential confounding" on the results of the retrospective case-control studies

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146 *Id.* at 3.

147 *Talc,* U.S. Food & Drug Administration (updated Aug. 18, 2020), *available at* https://www.fda.gov/cosmetics/cosmetic-ingredients/talc.

148 *Id.*

149 *Id.* at 6.

150 IARC 2010 Monograph at 412.

"could not be ruled out[,]" and that the results of the only prospective cohort study at the time did not support an association between talc and ovarian cancer,[151] IARC concluded that perineal use of talc-based body powder was possibly carcinogenic to humans. As a result of these conclusions, IARC gave talc a "Group 2B" classification,[152] which, under the IARC classification system meant that "there is limited evidence of carcinogenicity in humans and less than sufficient evidence of carcinogenicity in experimental animals."[153]

In April 2014, the FDA, following review of the First and Second Epstein Petitions (the "Petitions"), public comments received in response to the Petitions, and "additional scientific information," denied the Petitions due to a lack of "conclusive evidence of a causal association between talc use in the perineal area and ovarian cancer" or "that asbestos contaminated talc-containing cosmetic products are currently being marketed."[154] The FDA cited its own prior testing of commercially available products for asbestos, and the prior conclusion of a panel of experts at an FDA-sponsored workshop that the 1993 NTP study (cited in both Petitions) was not relevant to human risk. And despite acknowledging IARC's 2010 conclusion that there was limited evidence for the carcinogenicity of talc applied to the perineal area, the FDA found that "[r]esults of case-control studies do not demonstrate a consistent positive association across studies . . . dose-response evidence is lacking . . . [and a] cogent biological mechanism by which

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151 *Id.* Since the IARC 2010 Monograph was published, additional cohort studies have been published that also do not support an association between talc and ovarian cancer.

152 *Id.*

153 *Id.* at 35. There are four categories in total: Group 1 means that the "agent is carcinogenic to humans"; Group 2A means the "agent is probably carcinogenic to humans"; Group 2B means that the "agent is possibly carcinogenic to humans"; and Group 3 means the "agent is not classifiable as to its carcinogenicity to humans." *See* https://monographs.iarc.who.int/agents-classified-by-the-iarc/.

154 4/1/2014 FDA's 2014 denial of Citizen's Petition requesting warning on talcum powder products and related correspondence [Recently identified on publicly filed exhibit list in *Prudencio* at DX-17456] at 1, 3.

talc might lead to ovarian cancer is lacking[.]"[155] The FDA also noted that "the results of the Nurse's Health Study, a large prospective study, revealed no overall association with ever talc use and epithelial ovarian cancer."[156]

Following the first adverse talc-related damages award against J&J/Old JJCI in February 2016 (see discussion of *Fox* below), Old JJCI reached out to the FDA to discuss the verdict.[157] The FDA requested that Old JJCI provide it with "all safety literature and data regarding talc, including data in support of the safety of this active ingredient and data that shows potential harmful effects for this active ingredient[.]"[158] On March 17, 2016, Old JJCI responded with a comprehensive submission concerning the safety of Johnson's Baby Powder that included a summary of key published reviews of talc safety and ovarian cancer, relevant post-marketing talc safety data collected by Old JJCI (including data from its adverse event reports database), and information on talc chemistry, manufacturing, and controls.[159]

In May 2018, the FDA contacted Old JJCI to request information related to the company's methods for testing talc used in cosmetic products.[160] Specifically, the FDA requested information regarding (i) what methods Old JJCI used to detect the presence of

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155 *Id.* at 4-5.

156 *Id.* at 5.

157 3/17/2016 letter from J. Ekuta, D.V.M., Ph.D., RAC, FRAPS (J&J) to U.S. FDA re: Response to FDA Request for Information on Talc, JNJ 000639243-450.

158 2/25/2016 email from J. Adams-King (FDA) to L. Bryant (J&J) re: Information Request: Talc, JNJ 000636960-961.

159 3/17/2016 letter from J. Ekuta, D.V.M., Ph.D., RAC, FRAPS (J&J) to U.S. FDA re: Response to FDA Request for Information on Talc, JNJ 000639243-450. The company noted that "almost all" of the safety reports to the company concerning talc had been reported by or through attorneys involved in litigation against the company since 2014, and that clinical review of those cases "did not identify data to provide evidence to indicate a causal association between product use and ovarian cancer." *Id.*

160 5/25/2018 email from J. Ekuta (J&J) to L. Katz (FDA) re: Follow-up Regarding Your Request for a Teleconference with Johnson & Johnson Consumer Inc. (JJCI) Related to the Testing Methodology for Talc, JNJTALC000880349-353.

asbestos in talc; (ii) what standards or standardization procedures the company has in place to ensure that there are no asbestos particles in talc; and (iii) what "cut-off" is used by the company, if any, if asbestos is found in talc during testing.[161]

In a written submission to the FDA dated July 25, 2018, Old JJCI set forth detailed information concerning its standards and protocols related to talc testing, the methodologies used to ensure that its talc is not contaminated with asbestos, the testing that is conducted during the manufacturing process by its suppliers, the provisions of its supplier agreements relating to conformance with its talc-related standards and protocols, and the additional testing conducted as an audit by an independent third party lab.[162]

In 2017, the FDA again started an annual survey to test cosmetic talc products for the presence of asbestos. The FDA's ongoing testing of talc-based products continued into 2018 and 2019. Initially, those tests confirmed that Johnson's Baby Powder was not contaminated with asbestos.[163] Then, in October 2019, the FDA informed Old JJCI that a laboratory contracted by the FDA had claimed to find sub-trace amounts (<0.00002%) of chrysotile asbestos in a sample of Johnson's Baby Powder obtained by the FDA from Walmart.[164] Old JJCI immediately initiated a voluntarily recall of approximately 33,000 bottles of talc that had been manufactured in the same lot as the bottle tested, and launched a thorough investigation involving teams of

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161 *Id.*

162 7/25/2018 submission from J. Ekuta D.V.M., Ph.D., RAC, FRAPS (J&J) to U.S. FDA re: Response to FDA Request for Information on Johnson & Johnson's Testing of Cosmetic Talc, JNJTALC000880697-1978.

163 9/20/2019 Letter from L. Katz, MD, MPH (FDA), to L. Szczepaniak (J&J), JNJTALC001402492.

164 *Baby Powder Manufacturer Voluntarily Recalls Products for Asbestos*, U.S. Food & Drug Administration (Oct. 18, 2019), *available at* https://www.fda.gov/food/cfsan-constituent-updates/baby-powder-manufacturer-voluntarily-recalls-product-asbestos#:~:text=On%20October%2018%2C%202019%2C%20Johnson,of%20cosmetic%20products%20for%20asbestos).

personnel from across the company, as well as confirmatory testing of samples from the same bottle, the same lot, and surrounding lots by two third-party labs, Bureau Veritas Labs and RJ Lee.[165] Following that investigation, in December 2019, Old JJCI announced that its investigation had determined that there was no asbestos in the FDA bottle tested by AMA, eliminated the possibility that the Old JJCI talc supply chain introduced asbestos into its talc, and identified test sample contamination and/or analyst error as the most probable root causes of the FDA's initial finding.[166]

To date, the FDA has not concluded, based on its review of the scientific literature, that there is a causal relationship between talc and ovarian cancer, and has not recommended that consumers generally avoid talcum powder products. Other public health authorities that have evaluated the scientific literature relating to talc also have not concluded that the existing evidence demonstrates that perineal exposure to talc causes ovarian cancer.

F. Decades of J&J's and Old JJCI's Testing Establish the Safety of Their Products.

J&J's/Old JJCI's approach to talc testing is and has been state of the art. Not only does the company meet regulatory and industry standards, it exceeds those standards. The company's talc testing program begins with selective mining—carefully chosen and vetted sources for talc—and continues with layers of quality assurance testing at every point in the manufacturing and production chain, up to the moment of bottling.

Importantly, the company does not do this work alone. It relies on industry experts to

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165 12/3/2019 Johnson & Johnson Consumer Inc. Baby Powder Lot #22318RB Full Investigation Report [Recently identified on publicly filed exhibit list in *Prudencio* as DX-18901].

166 *Id.*

ensure its testing protocols are implemented at each stage of the process with a high level of precision and integrity. Indeed, it is precisely because the company's talc sourcing and testing program exceeds industry standards that dozens of government institutions, independent laboratories, and major universities that had studied and tested J&J's/Old JJCI's talc for decades before the current wave of cosmetic talc litigation time and again declared it free from asbestos.

1. Italian Talc

The earliest cosmetic talc at issue in the recent onslaught of litigation was sourced from Italy. J&J sourced its cosmetic talc from the Fontana mine in the Val Germanasca region of Italy from at least as early as the late 1920s through the late 1960s. In the 1950s and 1960s, J&J engaged the Battelle Memorial Institute ("Battelle") to examine the Italian talc, including subjecting the talc to optical microscopy testing. That testing at times identified "tremolite" in trace quantities but never identified asbestos in the Italian talc.[167]

In 1971 and 1972, when asbestos contamination in talcum powder began to be raised publicly as a possible concern, J&J engaged an expert mineralogist, Dr. Fred Pooley, of the geology department at the University of Cardiff in Wales, to conduct detailed studies of the Italian mine as well as samples of finished J&J product dating back to 1949. These analyses were conducted using a combination of x-ray diffraction (XRD), polarized light microscopy (PLM), and transmission electron microscopy (TEM).[168] In 1972, after a year of examining the Italian mine and the samples of products made with talc from that mine, Dr. Pooley's team confirmed that there was no asbestos in the mine or in any sample of J&J product made with talc

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167 *See e.g.*, 5/23/1958 Progress Report on the Physical Concentration of Talc Ores - Flotation to Johnson and Johnson JNJNL61_000001341-368.

168 10/17/1972 Letter from W. Nashed to R. Schaffner re Shower-To-Shower Brand Body Powder with attachment, JNJTALC000300260-496.

from the mine.[169] In addition to Dr. Pooley, AERE Harwell, the Mining Institute of Torino, Italy, and others also submitted reports to J&J on the Italian mine and/or tested samples of J&J talcum powder products made from Italian talc in the early 1970s.[170] J&J submitted those reports to the FDA in 1972.[171]

2. Vermont Talc

J&J began sourcing its cosmetic talc from Vermont in the mid-1960s. As with its Italian source, J&J engaged outside experts to analyze its Vermont cosmetic talc source. For example, in 1970, J&J commissioned CSM to conduct extensive core drilling and testing of the Hammondsville ore body—portions of which would be the primary source of cosmetic talc until it was exhausted as a source.[172] In 1971 and 1972, Dr. Pooley conducted a study of Vermont talc that was similar to his study of Italian talc, including by visiting the mines and testing samples of Vermont ore and talcum powder. He found that any amphiboles present in Vermont talc "were found in discrete locations and not disseminated throughout the talc ore and were not asbestiform in character," and that there were no chrysotile fibers in the talc.[173]

During this time, J&J also implemented routine testing protocols to analyze its talc for the presence of asbestos. As noted, in the 1970s, the FDA worked with the talc industry to develop what became the industry-standard method of testing for the presence of asbestos in

169 *Id.*

170 *Id.*

171 *Id.*

172 12/4/1970 Geological Audit for Windsor Minerals from the Colorado School of Mines Research Institute, JNJAZ55_000015127-286.

173 10/1972 F.D. Pooley, Report on the Examination of Rock Samples from the Vermont Mines and related correspondence, JNJ 000321606-654 at 48.

cosmetic talc: the two-step J4-1 standard.[174] The J4-1 standard starts with x-ray diffraction (XRD), which can determine the presence of an amphibole, but cannot confirm whether that amphibole is asbestos.[175] If XRD reveals an amphibole, the next step is polarized light microscopy (PLM).[176]

The company did not only use the J4-1 method. Beginning in the early 1970s, J&J also employed a rigorous program of routine testing that exceeded the J4-1 industry standard by also requiring testing using transmission electron microscopy (TEM), an even more powerful microscope.[177] J&J's/Old JJCI's testing required that it or its supplier take samples from every hour of every shift, of every work day, and combine them into composite samples to be tested by multiple methods.[178] The TEM analyses were performed by world renowned microscopy laboratory McCrone Labs—a lab even plaintiffs' expert Dr. William Longo called "literally the best lab in the country."[179] McCrone consistently did not find asbestos. As they reported in 1987, McCrone had "continuously monitored [the] composite samples" and concluded that the "product is free of asbestos" based on (at that time) "over 15 years of closely examining this product."[180]

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174 10/7/1976 CTFA Method J 4-1, Testing Monograph; Asbestiform Amphibole Minerals in Cosmetic Talc, Part I: X-ray Diffraction Method, Part II: Optical Microscopy and Dispersion-Staining Method, JNJ 000405219-228.

175 *Id.*

176 *Id.*

177 2/23/1978 J&J Letter to R. Miller re Windsor Minerals and Baby Products JNJ 000237200-201 at 1 ("[W]e intend [on] continuing to surpass the industry testing as reflected by CTFA's J4-1"); 6/28/1977 J&J Memorandum re Audit Testing of Windsor 66 Talc for Asbestos, JNJ 000252225-226 (showing TEM method TM 7024 in addition to applying J4-1).

178 2/23/1978 J&J Letter to R. Miller re Windsor Minerals and Baby Products JNJ 000237200-201.

179 8/13/2014 Dr. William Longo deposition testimony in *Fishbain, et al. v. Colgate-Palmolive Co., et al.*, (Super. Ct. N.J., Middlesex Cnty., No. MID-L-5633-13-AS) at 31:22-32:7.

180 5/21/1987 McCrone Letter from Stewart to Benninger re Monitoring Windsor's talc products, JNJ 000314361.

And, as time went on, Old JJCI added more steps to its testing and quality assurance process. By the 1990s, for example, Old JJCI required suppliers to produce a Certificate of Analysis with each shipment avowing that the talc has been tested and was not found to contain asbestos.[181]

3. Chinese Talc

Between 2003 and 2020, Old JJCI used Chinese talc for its talcum powder products sold in the U.S. The Chinese talc has at all times been subjected to rigorous, routine testing to confirm the absence of asbestos, and the routine testing has not uncovered the presence of asbestos in the talc. High grade un-milled ore was shipped to Old JJCI's supplier in the U.S. accompanied by a Certificate of Analysis confirming that the milled talc from the same source that was tested in China was free of detectable asbestos.[182] Upon arrival in the U.S., a composite sample would be collected and then tested by XRD, PLM, and TEM by Old JJCI's supplier, and the milled product was eventually sent to Old JJCI's external manufacturer Pharma Tech accompanied by a Certificate of Analysis confirming conformance with Old JJCI's specifications.[183] Additionally, each quarter since 2009 RJ Lee Group was added as an independent third-party lab to audit quarterly samples of milled talcum powder by XRD, PLM, and TEM methods.[184]

III. The Plaintiff Bar's Attempt To Create a New Mass Tort in Talc

Asbestos litigation is the longest running tort in American history. It already has undergone numerous iterations and waves, first focused on companies that made and sold

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181 8/21/1995 J&J Consumer Companies Worldwide Specification; Analysis of Powdered Talc for Asbestiform Minerals by Transmission Electron Microscopy, JNJ 000132581-589 (TM 7024 protocol).

182 12/3/2019 Investigation Report, JNJTALC001284148-6279.

183 *Id.*

184 *Id.*

products with substantial amounts of amphibole asbestos added as a component, like thermal insulation (the so-called "big dusties"). Then, once those companies largely sought relief in bankruptcy, plaintiffs shifted focus to secondary and tertiary defendants, such as chrysotile product manufacturers and other industrial manufacturers who may have incorporated third-party asbestos containing products in their equipment. The litigation has survived over 100 bankruptcies and spawned special dockets in nearly every state.

Yet, for law firms that derive their revenue exclusively from mesothelioma cases (and there are dozens),[185] recent trends in asbestos litigation have been concerning, if not outright threatening. As predicted by scientists in the 1990s and early 2000s, the incidence rate of mesothelioma has finally begun to flatten, if not fall.[186] And, given that the vast majority of industries in the United States stopped using asbestos by the 1980s, the number of mesothelioma claimants who can credibly allege any, let alone significant, exposure to asbestos has been steadily declining.

It is against the backdrop of this declining niche industry that J&J and Old JJCI have emerged as new prime litigation targets. Suddenly, a new white powder (not unlike asbestos itself for story telling purposes), and hope for yet another wave of the never-ending tort, materialized.

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185 *See, e.g.*, *Asbestos Lawyers,* Mesothelioma Lawyer Center, *available at* https://www.mesotheliomalawyercenter.org/asbestos-lawyer/; *Mesothelioma and Asbestos Law Firms*, The Mesothelioma Center (Asbestos.com), *available at* https://www.asbestos.com/mesothelioma-lawyer/law-firm/; *Mesothelioma Law Firm*, Mesothelioma.com *available at* https://www.mesothelioma.com/lawyer/law-firm/ for lists of such firms, organized state by state.

186 *National Program of Cancer Registries and Surveillance, Epidemiology, and End Results (SEER) Statistical Database: NPCR and SEER Incidence – U.S. Cancer Statistics 2001–2018 Public Use Research Database, 2020 submission (2001–2018),* U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute (June 2021), *available at* www.cdc.gov/cancer/uscs/public-use ("SEER Data").

A. As Traditional Asbestos Litigation Wanes for Firms that Have Profited from It for Decades, These Firms Instead Target Talc.

Prior to the 2010s, only a small number of isolated cases involving cosmetic talc had been filed against J&J or Old JJCI. These cases alleged a range of claims, including talcosis due to substantial misuse of Johnson's Baby Powder, mesothelioma, dermatitis, and rashes. Rarely was a J&J defendant seriously pursued in these cases.

Beginning in or around the early 1980s, certain J&J entities began to be named in a very small number of cases asserting allegations of respiratory injury caused by the use of Johnson's Baby Powder. The first such case that the company has located records for is *Joly v. Johnson & Johnson*, which was filed in 1982 in federal court in Louisiana and involved unspecified allegations of lung damage and respiratory problems resulting from the use of Johnson's Baby Powder. In 1983, *Gambino v. Johnson & Johnson Baby Prods. Co.* was filed, which involved allegations of talcosis, a type of pneumoconiosis caused by the excessive inhalation of talc. Of note, that case only implicated Johnson's Baby Powder, not Shower to Shower (which only began to be implicated when it became helpful for jurisdictional purposes, as described further below in the *Ingham* example). In total, there were less than a dozen additional cases naming J&J or Old JJCI and alleging injury from cosmetic talc throughout the 1980s and up to 1996. None of these cases implicated Shower to Shower.

The first case alleging mesothelioma as a result of exposure to Johnson's Baby Powder was *Howard as rep. of Cain v. A.I.I. Clubman Co.*, which was filed against Old JJCI (and other defendants) in Michigan state court in 1996. The following year, similar allegations were made in *Coker v. Bill Thames Pharmacy, Inc.*, filed in Texas state court. The J&J defendants were ultimately dismissed from these cases. Over the course of the late-1990s, 2000s, and early-2010s, various J&J entities were named in no more than a dozen additional cases alleging

mesothelioma as a result of exposure to Johnson's Baby Powder.[187] None of the cases involved allegations of Shower to Shower use.

1. The *Berg* and *Fox* Cases Launch a New Cosmetic Talc Litigation Industry.

The current tidal wave of cosmetic talc litigation began after the *Berg* (2013) and *Fox* (2016) trials. *Berg v. J&J*, filed in December 2009, was the first case alleging ovarian cancer as a result of genital exposure to J&J's/Old JJCI's cosmetic talc-based products. *Berg* involved a plaintiff who developed high grade serous ovarian cancer at the age of 49. The plaintiff found her lawyer through an ovarian cancer support website as she was looking for "the cause" of her cancer. The plaintiff's lawyer, who happened to be monitoring that website, responded to Ms. Berg's post seeking answers to her questions. He informed her that he knew the cause of her cancer—even though her own gynecologic oncologist had told her that the cause was unknown. He blamed Johnson's Baby Powder and Shower to Shower and filed a complaint on her behalf shortly thereafter.

Berg was tried in federal district court in South Dakota. The jury found for the plaintiff, but awarded *no* damages. Still, the plaintiff verdict sent ripples through the plaintiff bar, setting plaintiff lawyers on the road to a new mass litigation. Following *Berg*, plaintiff lawyers launched an extensive marketing campaign to collect ovarian cancer cases. They advertised on their firm websites and through spam emails, commercials, infomercials, and social media throughout the country. Records suggest that over the next few years, plaintiff firms spent as much as $4.5 million *per month* on cosmetic talc litigation advertising.[188] The plaintiff bar's

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187 December 5, 2018 Affidavit of Gene Williams in *Leavitt v. Johnson & Johnson*, Case No. RG17882401, Superior Court of the State of California, Alameda County.

188 *See, e.g.,* 10/2/2016 X Ante Report, "Talcum Powder: St. Louis Mass Tort Television Advertising Update, January-September 2016."

advertising campaign resulted in over 1,300 ovarian cancer lawsuits being filed against J&J and/or Old JJCI by the end of 2015. Indeed, in the years that followed the *Berg* verdict, tens of thousands of cases were filed all over the country, resulting in a federal multi-district litigation ("MDL") in New Jersey and multiple state consolidations.

A large number of those cases were strategically filed in state courts in the City of St. Louis, where they were bundled into multi-plaintiff cases. Plaintiffs' counsel joined multiple unrelated plaintiffs in several separate lawsuits, limiting the number of plaintiffs in each suit to avoid triggering federal class action jurisdiction, but also including in each suit at least one plaintiff from Missouri in the attempt to confer venue in the city of St. Louis, as well as at least one plaintiff from New Jersey so as to defeat federal diversity jurisdiction.

In February 2016, the first St. Louis ovarian cancer case, *Fox*, went to trial. *Fox* involved a plaintiff from the state of Alabama who had never lived in or visited the state of Missouri. The jury awarded the plaintiff $72 million dollars. While ultimately overturned on appeal, the verdict sparked even more interest on the part of plaintiff lawyers, who continued to push for trials in St. Louis. Five more cases were tried in that venue over the next year and a half, resulting in plaintiff verdicts totaling more than $235 million dollars (in addition to a defense verdict and a mistrial). All of those verdicts subsequently were reversed on appeal, but there was no turning back and no preventing the inevitable. Ultimately, as further discussed below, the 22-plaintiff *Ingham* trial was allowed to proceed in the City of St. Louis in January 2018. That trial resulted in J&J/Old JJCI receiving the fifth largest personal injury verdict in the history of the United States—a plaintiff verdict of $4.69 billion.[189]

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189 *See, e.g.*, *10 of the Largest Personal Injury Verdicts & Settlements in History*, Oasis Financial, *available at* https://www.oasisfinancial.com/largest-personal-injury-verdicts-settlements-in-history/.

Regardless of whether or not they were reversed, the large plaintiff verdicts in the ovarian cancer cases galvanized the plaintiff bar's ovarian cancer case collection frenzy, which continues to this day. As of the petition date, plaintiff lawyers had filed ovarian cancer lawsuits against J&J/Old JJCI on behalf of approximately 38,000 plaintiffs. Of course, ovarian cancer claims are only part of the story.

New filings alleging Johnson's Baby Powder as one, and then ultimately as the primary, cause of mesothelioma also skyrocketed. At the time of the *Fox* trial, there were only 6 mesothelioma cases naming J&J or Old JJCI as a defendant and alleging Johnson's Baby Powder as a cause of the plaintiff's disease. Within two months of the *Fox* trial, that number had increased to 23 mesothelioma cases. By the beginning of 2017, more than 100 mesothelioma cases had been filed naming J&J or Old JJCI as a defendant. The number of mesothelioma cases steadily grew in the years that followed. Seemingly overnight, experts who for years had every opportunity to point to cosmetic talc as a cause of mesothelioma—but never did—had a change of heart. Now, based on no new or compelling science, those same experts opined that it was allegedly sub-trace levels of asbestos in Johnson's Baby Powder that caused a plaintiff's mesothelioma.[190]

Whereas public reporting on mesothelioma filings had once shown a steady downward trend year to year from 2016 forward,[191] now, the asbestos plaintiff bar had a new source of cases to monetize and backfill the gap. While traditional mesothelioma filings have dipped by

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190 Mesothelioma cases predominantly have pointed to Johnson's Baby Powder as a cause of mesothelioma, but also have implicated Shower to Shower on occasion.

191 *See National Trends in Asbestos Litigation*, KCIC (May 6, 2021), as well as *Asbestos Litigation: 2020 Year in Review*, KCIC (2021) at 3. KCIC is a third party which tracks filings on behalf of dozens of defendants in asbestos litigation and reports aggregate filing statistics on an annual basis, including at public conferences attended by plaintiffs' counsel and members of the judiciary.

100 or so new cases per year,[192] mesothelioma filings against J&J/Old JJCI have more than made up the difference with 257 cases filed in 2017, 371 cases filed in 2018, 326 cases filed in 2019, 271 cases filed in 2020, and over 120 cases filed in 2021 (to-date).

2. The Asbestos Mass Tort Bar Adjusts Its Strategy to Talc.

As cosmetic talc litigation ramped up, the plaintiff bar adjusted its strategy to ensure that this new mass tort would endure as traditional asbestos litigation began to subside. From January 2016 through September 2020, 61.5% of the mesothelioma cases filed against J&J/Old JJCI were mixed exposure cases, meaning that the J&J defendants were simply added as an additional defendant to a mesothelioma case that also alleged exposure to traditional asbestos-containing products. 71% of these mixed exposure cases were filed in Madison County, Illinois—historically, a plaintiff-favored jurisdiction for asbestos litigation where most cases end in settlement.

However, as the cosmetic talc litigation continued, plaintiffs began filing more and more "talc-only" mesothelioma cases in other jurisdictions. Over the last year, only 32% of the new mesothelioma cases filed against J&J/Old JJCI have been mixed exposure cases; meaning, the vast majority of the cosmetic talc cases filed against J&J/Old JJCI are now "talc-only" cases. The reason for this shift in filing practices is purely strategic. By focusing the case on talc-only allegations and minimizing plaintiffs' exposure to traditional asbestos products (examples of which are further described below), plaintiffs strip talc defendants like Old JJCI of alternative exposure defenses, which are key in mesothelioma cases. As a result, Old JJCI was forced to undertake extensive and expensive investigations to uncover information regarding a plaintiff's alternative asbestos exposures. Moreover, these "talc-only" cases are perceived to be insulated

192 *Id.*

from the threat that traditional asbestos companies may disappear from active tort litigation.

The following are just a few examples of the sorts of cases filed to implement the "talc-only" strategy:

- In one trial, plaintiff's counsel and experts focused their case on allegedly sub-trace levels of asbestos in Johnson's Baby Powder, despite the fact that the plaintiff had for years smoked Kent asbestos-containing cigarettes. Each Kent cigarette that the plaintiff smoked would have contained 80 billion fibers of the deadliest type of asbestos, crocidolite.

- In another trial, neither side disputed that the plaintiff had handled asbestos-containing brakes, had been present when her husband removed and sanded those brakes, and that she then laundered his asbestos-covered clothes. Plaintiff expert Dr. Longo had previously testified in traditional asbestos litigation that sanding brakes, which he alleged were designed to contain 80% asbestos, was "like hitting a pinata of dust." But now with J&J/Old JJCI as the primary litigation target, Dr. Longo downplayed the brake exposures, opining that the allegedly sub-trace levels of asbestos in Johnson's Baby Powder resulted in higher exposure levels. Ultimately, in that trial, the jury returned a verdict of $25.75 million against J&J and Old JJCI, finding that they were 67% at fault.

- One of the most frequent plaintiff causation experts in mesothelioma cases is Dr. Jacqueline Moline. In one case, Dr. Moline issued a report with her opinion that Johnson's Baby Powder caused a particular plaintiff's mesothelioma, but did not conduct the most basic of investigations, which would have revealed that the plaintiff lived, went to school, and worked 1.5 kilometers from an asbestos cement factory.

B. The Lack of Support for Ovarian Cancer Claims Caused by Talc

1. What is Ovarian Cancer?

Ovarian cancer comprises several distinct diseases, which are categorized into separate subtypes. These different types of ovarian cancer develop in different types of cells, they look different under a microscope, they involve mutations of different genes, and they have different risk factors and causes. Notably, in the largest prospective analysis of ovarian cancer risk factors ever conducted—pooling individual data for more than 1.3 million women from 21 studies—researchers who considered 14 risk factors found that "[e]ach subtype [of ovarian cancer] had a qualitatively unique pattern of associations" and that "[o]nly parity and height were associated

with all subtypes."[193] This study concluded that "subtypes are indeed different diseases" with different risk factors that need to be evaluated.[194] The idea that a single commercial product, such as cosmetic talc, could cause all of these different types of ovarian cancer is nonsensical. Nevertheless, plaintiffs continue to argue that these numerous different subtypes of ovarian cancer have an identical cause.

2. Plaintiffs Cannot Reasonably Establish Causation

To prevail in a tort case, plaintiffs have to prove both general causation—whether a certain exposure (such as talcum powder) is capable of causing a disease (such as ovarian cancer or mesothelioma)—and specific causation—whether the particular exposure caused the individual plaintiff's disease.[195] Plaintiffs generally have a low hurdle to cross in establishing exposure to J&J/Old JJCI talcum powder products given the ubiquity of these products in the community.[196] Thus, in most cases, the causation debate focuses on whether the use of cosmetic talcum powder products can cause ovarian cancer.

Plaintiffs' primary mechanistic theory is that talc applied to the perineum can migrate through the female reproductive tract to the ovaries, where it causes a chronic inflammatory

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193 Wentzensen et al., *Ovarian Cancer Risk Factors by Histologic Subtype: An Analysis from the Ovarian Cancer Cohort Consortium*, 34 J. CLIN. ONCOLOGY 2888, 2889-2890, 2894 (2016) ("Wentzensen 2016"); *see e.g., id.,* at 2888 (abstract) ("The heterogeneous associations of risk factors with ovarian cancer subtypes emphasize the importance of conducting etiologic studies by ovarian cancer subtypes."); Bodelon et al., *Molecular Classification of Epithelial Ovarian Cancer Based on Methylation Profiling: Evidence for Survival Heterogeneity*, 25 CLIN CANCER RES. 5937, 5937 (abstract) (2019) ("Ovarian cancer is a heterogeneous disease that can be divided into multiple subtypes with variable etiology, pathogenesis, and prognosis.").

194 Wentzensen 2016 at 2895-96.

195 *Howell v. Centric Group, LLC*, 508 Fed. Appx. 834, 836 (10th Cir. 2013) ("when such claims target allegedly toxic substances or pharmaceuticals, courts throughout the country routinely require plaintiffs to show both general and specific causation"); *see also* RESTATEMENT (THIRD) OF TORTS: PHYS. & EMOT. HARM § 28 (2010) ("The concepts of general causation and specific causation are widely accepted among courts confronting causation issues with toxic agents.").

196 *But, see,* section IV.B.4, *infra*, with respect to examples of unsubstantiated claims.

response that leads to ovarian cancer. To explain cause and effect, plaintiffs rely on the case-control studies described previously, some of which report a positive, albeit weak, association between talc and ovarian cancer.[197] However, as noted, these studies are subject to substantial criticism for several reasons. First, half of the case-control studies fail to show a statistically significant association, rendering the totality of evidence from case-control studies inconsistent and insufficient to prove causation. Second, the case-control studies that are most supportive of plaintiffs' theory do not reflect a strong association. Third, the case-control studies relied upon by plaintiffs conflict with the findings in the four large, prospective, cohort studies that have been conducted to date, none of which shows a statistically significant overall association between talc use and ovarian cancer. Fourth, although plaintiffs claim that there is "some" evidence in the case-control studies of a dose-response, they "freely admit that the dose response data . . . are not unequivocal."[198] Finally, although plaintiffs describe a biological mechanism by which they claim that talc can reach the ovaries, that theory is unsupported by any published studies showing that talc applied externally to the genitals, as alleged by plaintiffs, can migrate to the ovaries through the female reproductive system.

3. Application of Key Bradford Hill Factors

Scientists, as well as courts, rely on a set of guidelines known as the Bradford Hill criteria[199] to determine whether an alleged statistically significant association between an

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197 *See* section II.D, *supra*.

198 5/31/2019 Plaintiffs' Corrected Omnibus Memorandum of Law in Response and Opposition to Defendants Motion to Exclude Plaintiffs' General Causation Opinions, *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs. & Prods. Liab. Litig.*, (D.N.J. MDL No. 16-2738 (FLW) (LHG)), Dkt. 9914 (hereinafter "Pls. GC Opp.") at 161.

199 The English epidemiologist, Sir Austin Bradford Hill, published the "Bradford Hill" criteria in 1965. Sir Austin Bradford Hill, *The Environment and Disease: Association or Causation?*, 58 PROC. R. SOC. MED. 295, 296 (1965).

exposure and a disease is strong enough to potentially support an inference of general causation of the disease by such exposure.[200] Epidemiological evidence, alone, can never prove specific causation.[201] Four of the Bradford Hill criteria—strength of association, consistency with other relevant knowledge, dose-response relationship, and biological plausibility—are of particular significance in assessing plaintiffs' claim that peritoneal talc exposure causes ovarian cancer, **and all weigh against plaintiffs' causation theory**.[202]

a. Strength of the Association

Strength of association refers to relative risk—"[t]he higher the relative risk, the stronger the association and the lower the chance that the effect is spurious" (non-causal or the result of confounding, biases, or other error).[203]

As noted, the Debtor is aware of 34 case-control studies—27 population-based and 7 hospital-based—assessing a relationship between talc and ovarian cancer, four cohort studies, and ten meta-analyses and pooled analyses (which synthesize results of available studies on this topic).[204] Plaintiffs contend that when the studies are viewed in totality, the data shows a

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200 *See e.g., Jones v. Novartis Pharm. Corp*., 235 F. Supp. 3d 1244, 1274 (N.D. Ala. 2017), *aff'd in part sub nom. Jones v. Novartis Pharm. Co*., 720 Fed. Appx. 1006 (11th Cir. 2018) (unpublished) ("Numerous courts have referred to the Bradford Hill criteria as a useful tool to analyze general, rather than specific, causation."); *In re Breast Implant Litig*., 11 F. Supp. 2d 1217, 1233 n. 5 (D. Colo. 1998) ("Even if the epidemiology demonstrated that breast implants double the risk of disease . . . Plaintiffs' causation experts must still satisfy the additional Bradford–Hill criteria to establish scientific cause and effect."); *King v. Burlington N. Santa Fe Ry. Co*., 762 N.W.2d 24, 39 (Neb. 2009) ("Once an association has been found between exposure to an agent and development of a disease, researchers consider whether the association reflects a true cause-effect relationship.") (quoting Green 2011 at 597)).

201 Green 2011 at 608–09 (explaining that specific causation "is beyond the domain of the science of epidemiology").

202 The first Bradford Hill factor, temporal relationship, is not contested here. Plaintiffs routinely allege—and, typically, it is difficult to refute—exposure to talcum powder products that occurred before they developed ovarian cancer.

203 Green 2011 at 602.

204 *See* section II.D, *supra*.

consistent, statistically significant increased risk of developing ovarian cancer with perineal talcum powder use.

However, not one of those studies reported a statistically significant relative risk of 2.0 or more, the threshold for legal causation in many jurisdictions.[205] Biases and confounding factors may fully explain observed association when the relative risk is less than 2.0.[206] Because case-control studies are retrospective in nature and rely on subjects' recall of the extent or nature of their exposure, they are more likely than cohort studies to report a false association as a result of recall bias and confounding.

Recall bias is especially problematic when studying talc use because it is exceedingly difficult for study subjects to accurately report the extent of their use, which "require[s] subjective summarization or can be influenced by the investigator, media or similar factors."[207] Many talc studies did not blind participants to the purpose of the study; as a result participants may well have been alerted to the fact that talc was of interest and affected by that recognition.[208]

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205 *See, e.g.*, *Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 591 (D.N.J. 2002), *aff'd*, 68 F. App'x 356 (3d Cir. 2003) ("[T]he threshold for concluding that an agent was more likely than not the cause of an individual's disease is a relative risk greater than 2.0.") (citation omitted).

206 Green 2011 at 612-13 n. 193.

207 Peres et al., *Racial/ethnic differences in the epidemiology of ovarian cancer: a pooled analysis of 12 case-control studies*, INT'L J EPIDEMIOLOGY 460, 469 (2018). O'Brien 2020 states that the positive association reported in the case-controls "may be affected by recall bias," and "it is crucial to evaluate the talc-ovarian cancer association using prospective data." O'Brien 2020 at 50. Even Berge 2018, one of the meta-analyses on which plaintiffs' rely, notes that the association present in the case-control but not cohort studies, "can be attributed to bias in the former type of studies." Berge 2018 at 253.

208 2/25/2019 Expert Report of Dr. Karla Ballman, Ph.D. for General Causation *Daubert* Hearing in *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs. & Prods. Liab. Litig.*, (D.N.J. MDL No. 16-2738 (FLW) (LHG)), Dkt. 9740-24 ("Ballman Rep.") at 7; 11/16/2018 Expert Report of Dr. Patricia G. Moorman, M.S.P.H., Ph.D. in *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs. & Prods. Liability Litig.*, (D.N.J. MDL No. 16-2738 (FLW) (LHG)), Dkt. 9740-34 at 21-22 ("recall bias would be considered a particular threat to a study's validity" where, inter alia, "the study hypotheses are known to the study subjects or interviewers"); 11/16/2018 Expert Report of Sonal Singh, M.D., M.P.H. in *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs. and Prods. Liability Litig.,* (D.N.J. MDL No. 16-2738 (FLW) (LHG)), Dkt. 9740-39 at 11 ("Case-control studies, by their design, are generally not blinded and are also susceptible to bias as a result.").

One study found "women with [ovarian] cancer tend to remember or overreport their use of body powder" and the "influence of this type of recall bias cannot be ruled out."[209] With respect to talc in particular, recall bias may have been increased by media coverage of the talcum powder litigation.[210] While it is impossible to measure the full extent of recall bias in the studies plaintiffs rely upon for their causation claims, recall bias is a well-recognized, inherent problem with case-control studies.[211]

The case-control studies may also be unreliable measures of association because of confounding (*i.e*. the existence of study participants who have risk factors for ovarian cancer unrelated to talc).[212] Adjusting for confounding is particularly important in the ovarian cancer context because most cases of ovarian cancer have no known cause and other risk factors can account for positive associations in observational studies.[213]

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209 Langseth 2008 at 358.

210 In the Schildkraut case-control study published in 2016, women with ovarian cancer who were interviewed for the study after 2014 (when talc lawsuits began receiving more significant media attention) reported markedly higher talc use than those interviewed before 2014, while reported talc use for controls was essentially the same regardless of when they were interviewed. Schildkraut et al., *Association between Body Powder Use and Ovarian Cancer: The African American Cancer Epidemiology Study*, 25(10) CANCER EPIDEMIOLOGY, BIOMARKERS & PREVENTION 1411, 1413 (2016) ("Schildkraut 2016"). Schildkraut found no statistically significant association between talc use and ovarian cancer in the women who were interviewed before 2014. *Id.*

211 *See* Green 2011 at 585.

212 *See id.* at 602.

213 *See, e.g*., 1/31/2019 Dr. Jack Siemiatycki deposition testimony in *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs. & Prods. Liab. Litig.*, (D.N.J. MDL No. 16-2738 (FLW) (LHG)), Dkt. 9733-3 at 173:6-9 (agreeing that "all of the factors that might make someone susceptible to developing ovarian cancer are not currently known"); 2/25/2019 Expert Report of Dr. Kevin Holcomb, M.D., F.A.C.O.G. for General Causation *Daubert* Hearing in *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs. & Prods. Liability Litig.,* (D.N.J. MDL No. 16-2738 (FLW) (LHG)), Dkt. 9740-26 at 12 (explaining that unknown factors can account for associations previously attributed to different factors); 2/25/2019 Expert Report of Dr. Gregory Diette, M.D., M.H.S. for General Causation *Daubert* Hearing in *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs. & Prods. Liability Litig.,* (D.N.J. MDL No. 16-2738 (FLW) (LHG)), Dkt. 9740-17 ("Diette Rep.") at 4 ("confounding factors are not always identifiable, even after extended study, and these and other factors can consistently drive statistical associations that are not causal in nature"). Other studies list a high BMI and douching as potential risk factors for ovarian cancer, but the vast majority of the case-control studies did not control for those characteristics. 2/25/2019 Expert Report of Dr. Christian Merlo, M.D., M.P.H. for General Causation *Daubert* Hearing in *In re Johnson &*

Plaintiffs also rely heavily on meta-analyses and pooled studies that combine the results of several studies (often both case-control *and* cohort studies). However, meta-analyses come with their own problems and limitations. First, meta-analyses do not correct for, and may even exacerbate, issues in the underlying studies, including recall bias and confounding.[214] Second, meta-analyses combining different *types* of studies, conducted in different ways, can often lead to misleading results.[215] Many of the meta-analyses that plaintiffs rely on—including Taher (2019),[216] Penninkilampi 2018, and Berge 2018, analyze case-control *and* cohort studies together. Critics of meta-analyses warn of this type of "apples to oranges" comparison[217] and caution that "[s]ummarizing large amounts of varied information" can lead to "misleading results."[218] In sum, while meta-analyses can be a useful tool for evaluating epidemiologic data, they are limited by the quality of the underlying studies and the methodology for study inclusion.

Johnson Talcum Powder Prods. Mktg. Sales Pracs. & Prods. Liability Litig., (D.N.J. MDL No. 16-2738 (FLW) (LHG)), Dkt. 9740-12 ("Merlo Rep.") at 13. Gonzalez 2016 suggested that douching—not talc use—might account for the association observed in case-control studies. Gonzalez 2016 at 797. Gonzalez found that talc users are more likely to douche than the general population and that douching nearly doubled the risk of ovarian cancer, yet only a couple of case-control studies have adjusted for douching. *Id.*

214 Merlo Rep. at 30.

215 *See, e.g.*, Walker et al., *Meta-analysis: Its Strengths and Limitations,* 75(6) CLEV. CLINIC J. MED. 431, 433 (2008) ("Walker 2008") (explaining that when selecting studies to include in a meta-analysis, they should be "as similar as possible" because "even with careful selection, differences among studies will remain" and "when the dissimilarities are large it becomes hard to justify pooling the results to obtain a 'unified' conclusion").

216 Taher et al., *Systematic Review and Meta-Analysis of the Association between Perineal Use of Talc and Risk of Ovarian Cancer*, 29 REPROD. TOXICOL. 88 (2018).

217 Esterhuizen et al., *Con: Meta-analysis: Some Key Limitations and Potential Solutions*, 31 NEPHROL. DIAL. TRANSPLANT 882, 882-885. (2016).

218 Walker 2008 at 431. Even the authors of Berge 2018 acknowledged that the "study suffers from limitations common to meta-analyses of observational studies" including the fact that "neither the definition of the exposure of interest (genital talc use) nor the strategy for adjustment of potential confounders were fully consistent across studies." Berge 2018 at 255.

b. Consistency with Other Relevant Knowledge

The 17 population-based case-control studies that purport to show a statistically significant association between talc and ovarian cancer are not consistent with the findings of other studies among different populations and with different study designs. As noted, not one of the seven hospital-based case-control studies (which used as controls women referred to the same medical facility for reasons other than ovarian cancer) found a statistically significant association. That is particularly important because case-control studies using hospital controls are less likely to have results distorted by recall bias than studies with population controls.[219] Additionally, the prospective cohort studies, the Nurse's Study (Gertig 2000 and Gates 2010), the Women's Health Initiative Study (Houghton 2014), and the Sister Study (Gonzalez 2016) showed no overall association between perineal talc use and ovarian cancer.

c. Dose-Response Relationship

Dose-response relationship refers to the strength of the expectation that increased exposure to a causal agent will lead to an increased incidence and/or increased severity of the disease. Dose-response has been described by some courts as the "hallmark of basic toxicology" and "the single most important factor to consider in evaluating whether an alleged exposure caused a specific adverse effect."[220]

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219 Diette Rep. at 19.

220 *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1242 (11th Cir. 2005) (quoting David L. Eaton, *Scientific Judgement and Toxic Torts - A Primer in Toxicology for Judges and Lawyers*, 12 J. L. & POL'Y 5,11 (2003) ("Eaton 2003")). In *McClain*, the court reversed a jury verdict after concluding that the district court erroneously admitted plaintiffs' expert testimony on causation where that expert did not provide satisfactory testimony on the dose-response relationship. *See also In re Accutane Products Liab.*, 511 F. Supp. 2d 1288, 1293 (M.D. Fla. 2007) ("[d]ose is critical to any evaluation of toxicity of a drug"); *Smith v. Benjamin Moore & Co.*, 2012 WL 2914219, at *2 (Del. Super. July 18, 2012) (explaining that "[t]he Texas Supreme Court has noted that dose is the single most important factor to consider in evaluating whether an alleged exposure caused a specific adverse effect") (internal quotations omitted).

Plaintiffs assert that there is evidence of a dose-response effect between talc and ovarian cancer but they "freely admit that the dose response data . . . are not unequivocal."[221] Plaintiffs only point to eight of the studies as supportive of the presence of a dose-response relationship between talc use and ovarian cancer.[222] But these studies taken as a whole do not reflect a consistent dose-response relationship between talc use and ovarian cancer, and the total body of evidence on dose response contradicts plaintiffs' findings.[223] Plaintiffs merely extract evidence of a dose response from a subset of studies (and even from subsets of data within these cherry-picked studies), even though the body of data clearly does not show a dose response.[224] Of the subset of case-control studies that looked at dose-response, at least thirteen reported no

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221 Pls. GC Opp. at 161.

222 *Id.* at 161-62 (listing Penninkilampi 2018; Berge 2018; Schildkraut 2016; Cramer et al., *The Association Between Talc Use and Ovarian Cancer: A Retrospective Case-Control Study in Two US States*, 27(3) EPIDEMIOLOGY 334 ("Cramer 2016"); Terry et al., *Genital Powder User and Risk of Ovarian Cancer: A Pooled Analysis of 8,525 Cases and 9,859 Controls*; 6(8) CANCER PREV. RES. 811 (2013); Wu et al., *Markers of Inflammation and Risk of Ovarian Cancer in Los Angeles County*, 124 INT'L J. CANCER 1409 (2009); Whittemore et al., *Personal And Environmental Characteristics Related To Epithelial Ovarian Cancer*, 128 AM. J. EPIDEMIOLOGY 1228 (1988) ("Whittemore 1988"); Rosenblatt et al., *Mineral Fiber Exposure and the Development of Ovarian Cancer*, 45(1) GYNECOLOGIC ONCOLOGY 20 (1992) ("Rosenblatt 1992")).

223 Merlo Rep. at 45 ("Almost every epidemiological study has failed to show any dose-response relationship[.]"); Diette Rep. at 27 ("[O]verall, the literature is very inconsistent with regard to dose-response, as Drs. Smith-Bindman and Moorman concede;" further noting none of the cohort studies and only a handful of case-control studies purport to have found a dose response); Ballman Rep. at 30-32 & tbls. 1 & 2 (summarizing dose-response findings from various studies, very few of which reported a dose response).

224 *Compare, e.g.*, 11/16/2018 Expert Report of Dr. Anne McTiernan, M.D., Ph.D. in *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs. & Prods. Liability Litig.,* (D.N.J. MDL No. 16-2738 (FLW) (LHG)), Dkt. 9740-6 ("McTiernan Rep.") at 66 ("significant" evidence of a causal relationship), and 11/16/2018 Expert Report of Dr. Jack Siemiatycki, M.Sc., Ph.D. in *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs. & Prods. Liability Litig.,* (D.N.J. MDL No. 16-2738 (FLW) (LHG)), Dkt. 9740-20 at 63 (referring to dose response as "an important consideration in my assessment of causality"), *with, e.g.*, 11/16/2018 Expert Report of Ellen Blair Smith, M.D. in *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs. & Prods. Liability Litig.,* (D.N.J. MDL No. 16-2738 (FLW) (LHG)), Dkt. 9740-15 at 20 (additional research needed to "help clarify dose response relationships"), and 11/16/2018 Expert Report of Daniel L. Clarke-Pearson, M.D. in *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs. and Prods. Liability Litig.,* (D.N.J. MDL No. 16-2738 (FLW) (LHG)), Dkt. 9740-13 at 9 (calling for molecular research to "elucidate" dose response).

dose-response.[225] In addition, data from the cohort studies that looked at frequency or duration of talc use found no evidence of a dose response. After an evaluation of the scientific evidence, the 2021 National Cancer Institutes' ("NCI") Physician Data Query[226] reported that a "dose response relationship was not found" and "there was no increased risk observed for increasing duration of use."[227] The IARC also noted "inconsistent" evidence of a dose response[228] and in 2014, the FDA concluded in response to the Epstein Citizen's Petitions that "dose-response evidence was lacking."[229]

d. Biological Plausibility

Biological plausibility asks whether there is a valid, scientifically plausible method through which the agent could cause the disease, in light of existing scientific knowledge about the mechanism by which the disease develops. One of the key scientific criteria used to

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225 *See* Whittemore 1988; Booth et al., *Risk factors for ovarian cancer: a case-control study*, 60(4) BR. J CANCER 592 (1989); Rosenblatt 1992; Hartge et al., *Occupation and Ovarian Cancer: A Case-Control Study in the Washington, DC, Metropolitan Area, 1978-1981*, 36(8) J OCCUP MED. 924 (1994); Chang & Risch, *Perineal talc exposure and risk of ovarian carcinoma*, 79(12) CANCER 2396 (1997); Cook et al., *Perineal Powder Exposure and the Risk of Ovarian Cancer*, 145(5) AM. J. EPIDEMIOLOGY 459, 463 (1997); Cramer et al., *Genital Talc Exposure and Risk of Ovarian Cancer*, 81(3) INT J CANCER 351 (1999); Wong et al., *Perineal talc exposure and subsequent epithelial ovarian cancer: a case-control study*, 93 OBSTET GYNECOl 372 (1999); Ness et al., *Factors Related to Inflammation of the Ovarian Epithelium and Risk of Ovarian Cancer*, 11(2) EPIDEMIOLOGY 111 (2000); Mills et al., *Perineal Talc Exposure and Epithelial Ovarian Cancer Risk in the Central Valley of California*, 112(3) INT'L J. CANCER 458 (2004); Merritt et al., *Talcum Powder, chronic pelvic inflammation and NSAIDs in relation to risk of epithelial ovarian cancer*, 122 INT'L J. CANCER 170 (2008); Rosenblatt et al., *Genital powder exposure and the risk of epithelial ovarian cancer*, 22 CANCER CAUSES CONTROL 737 (2011); Cramer 2016 at 336-37 tbl. 1.

226 According to the NCI's website, "PDQ (Physician Data Query) is NCI's comprehensive source of cancer information. It contains cancer information summaries on a wide range of cancer topics; drug information summaries on many cancer-related drugs and drug combinations; and dictionaries of general cancer terms, drug terms, and genetics terms." *See PDQ® - NCI's Comprehensive Database*, NAT'L CANCER INST., *available at* https://www.cancer.gov/publications/pdq (last updated August 11, 2021).

227 NCI 2021 PDQ.

228 IARC 2010 Monograph at 412.

229 4/1/2014 FDA's 2014 denial of Citizen's Petition requesting warning on talcum powder products and related correspondence [Recently identified on publicly filed exhibit list in *Prudencio* as DX-17456] at 4 (arguing that "dose-response ***evidence is lacking***") (emphasis added).

"establish causation between an alleged [] exposure and a particular disease or illness" is that "[t]he chronological relationship between exposure and effect must be biologically plausible."[230]

Plaintiffs' primary theory of biological plausibility is that talc, when applied to the perineum, migrates up through the female reproductive system to the ovaries.[231] Once in the ovaries, plaintiffs claim that the talc causes chronic inflammation which then leads to ovarian cancer.

As their evidence that talc migrates through the female reproductive tract, plaintiffs cite to two types of studies: (i) experimental studies where particles placed into the genital tract migrated upward ("particle studies"), and (ii) pathological studies where researchers purported to identify talc in ovarian tissue samples of women.

Plaintiffs primarily rely on three particle studies in support of the theory that talc migrates.[232] However, none of those studies involved talc but instead involved other particles such as carbon or aluminum micro- or macro- spheres.[233] In addition, because the particles were

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230 Eaton 2003 at 38-39.

231 Although plaintiffs' expert witnesses have proffered (as an alternative theory) inhalation as a biological mechanism for talc to reach the ovaries (the inhaled talc could enter the lymphatic system and travel to the ovaries), in the MDL, Judge Wolfson held that "[a]side from these experts claiming that the inhalation theory may be plausible, [Plaintiffs] fail to otherwise provide any scientific basis for the theory that talc somehow moves through the lymphatic system to the ovaries." *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs. & Prods. Liab. Litig.*, 509 F. Supp. 3d 116, 176 (D.N.J. 2020) (the "April 27, 2020 MDL Order"). On that basis, Judge Wolfson excluded testimony on plaintiffs' theory of inhalation as a biological mechanism. *Id.* at 177.

232 Egli and Newton, *The Transport of Carbon Particles in the Human Female Reproductive Tract*, 12 FERTILITY AND STERILITY 151 (1961) ("Egli and Newton 1961"); Venter and Iturralde, *Migration of a Particulate Radioactive Tracer from the Vagina to the Peritoneal Cavity and Ovaries*, 55 SOUTH AFRICAN MED. J. 917 (1979) ("Venter and Iturralde 1979"); Sjösten et al., *Retrograde migration of glove powder in the human female genital tract,* 19(4) HUMAN REPROD. 991 (2004) ("Sjösten 2004").

233 *See, e.g.*, Zervomanolakis et al., *Physiology of Upward Transport in the Human Female Genital Tract*, 1101 Ann. N.Y. Acad. Sci. 1, 4 (2007) (radiolabeled microspheres); Sjösten 2004 at 991 (surgical glove starch powder, presumably cornstarch); Kadanali et al., *Evaluation of active and passive transport mechanisms in genital tracts of IUD-bearing women with radionuclide hysterosalpingoscintigraphy*, 63 CONTRACEPTION 41, 42 (2001) (radiolabeled albumin macrospheres); Kunz et al., *The Uterine Peristaltic Pump: Normal and Impeded Sperm Transport within the Female Genital Tract, in The Fate of the Male Germ Cell* 267 (Ivell & Holstein eds. 1997) (same); Iturralde & Venter, 11(4)

inserted inside women's bodies rather than dusted on the outside, they cannot provide any reliable support for the migration theory. Furthermore, many of the studies occurred in environments manipulated to encourage the movement of those particles further up the genital tract. Importantly, animal studies investigating retrograde movement—in which talc was used—did not result in evidence of migration to the ovaries.[234]

Plaintiffs also rely on four pathological studies and claim that those studies show the presence of talc and asbestos in human ovarian cells and lymph nodes.[235] The fact that talc was found in ovaries, however, says absolutely nothing about how the talc got there or where the talc came from since talc is ubiquitous and found in a number of commonly used products. The most that these publications show is that talc can be found in human ovaries or lymph nodes, but the studies do not come anywhere close to concluding that talc "applied to the perineum may be absorbed into the vagina and migrate . . . to the tubes and ovaries."[236]

Hysterosalpingo-radionuclide scintigraphy (HERS), SEM. NUCL. MED. (11)4:301-149 (1981) (radiolabeled albumin microspheres); Venter and Iturralde 1979 at 917 (same); De Boer, *Transport of Particulate Matter Through the Human Female Genital Tract*, 28 J REPROD. FERTILITY 295, 295 (1972) (colloidal carbon solution); Egli and Newton 1961 at 151 (carbon particles).

234 *See* Phillips et al., *Studies on the Absorption and Disposition of 3H-Labelled Talc in the Rat, Mouse, Guinea-Pig and Rabbit*, FD COSMET TOXICOL. 1978; 16:161-163 (intravaginal administration of talc in rabbits); Wehner AP and Weller RE, *On Talc Translocation From the Vagina to the Oviducts and Beyond*, FD CHEM TOXICOL. 1986; 24:(4):329-338 (intravaginal administration in monkeys); and Boorman GA and Seely JC, *The Lack of an Ovarian Effect of Lifetime Talc Exposure in F344/N Rats and B6C3F1 Mice*, REGUL TOXICOL PHARMACOL. 1995; 21(2): 242-3 (external vaginal exposure in rats).

235 Pls. BP Opp. at 16-18; Henderson et al., *Talc and Carcinoma of the Ovary and Cervix*, 78 J. of OBSTET. AND GYNAECOLOGY 266-268 (1971); Heller et al., *The relationship between perineal cosmetic talc usage and ovarian talc particle burden*, 174 AM. J. OBSTET. GYNECOL. 1507-1510 (1996); Heller et al., *Asbestos Exposure and Ovarian Fiber Burden*, 29 AM. J. OF INDUSTRIAL MED. 435-439 (1996); Cramer et al., *Presence of Talc in Pelvic Lymph Nodes of a Woman with Ovarian Cancer and Long-Term Genital Exposure to Cosmetic Talc*, 110(2) OBSTET. & GYNECOL. 498-99 (2007); McDonald et al., *Correlative polarizing light and scanning electron microscopy for the assessment of talc in pelvic region lymph nodes*, 43 ULTRASTRUCTURAL PATHOL. 13-27 (2019).

236 11/15/2018 Expert Report of Dr. Rebecca Smith-Bindman, M.D. in *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs. & Prods. Liability Litig.,* (D.N.J. MDL No. 16-2738 (FLW) (LHG)), Dkt. 9740-35 at 35; *see also* McTiernan Rep. at 59 (claiming these studies "demonstrate talcum powder products can migrate from the perineal area to the ovaries and fallopian tube"). Notably, in the MDL, Judge Wolfson found that the studies relied on by plaintiffs' expert witnesses "do not directly support their

Plaintiffs further assert that once talc allegedly reaches the ovaries, it causes inflammation, which then can lead to cancer.[237] However, this theory is undermined by available scientific evidence in several respects. The theory that inflammation can cause ovarian cancer is, at best, an unsubstantiated hypothesis. Indeed, efforts to support this hypothesis have failed. For example, studies have shown that anti-inflammatory drugs do not reduce the incidence of ovarian cancer.[238] And a case study involving lesions knowns as STICs that are recognized precursors of ovarian cancer concluded that they were not associated with inflammation.[239]

Plaintiffs' theory that talc could cause cancer is also undermined by the fact that talc is not mutagenic or genotoxic—a significant problem for biological plausibility. For example, a 2009 study treated rats intravaginally and perineally with talc and observed no neoplastic change (*i.e.*, no cancer), and a 1984 study injected talc directly into the rat ovarian bursa and similarly observed no malignancies.[240]

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theory that *externally applied* talc can migrate up the vagina to the ovaries." April 27, 2020 MDL Order at 174 (emphasis in original).

237 *See, e.g.*, Fiume 2015 at 119S (studies looking at occupational inhalational talc exposure do not show an increased risk of lung disease); Pira et al., *Mortality of Talc Miners and Millers from Val Chisone, Northern Italy: An Updated Cohort Study*, 59 J. OCCUPATIONAL AND ENV'T MED. 659 (2018) ("Pira 2018") (concluding that there was a lack of association between exposure to asbestos-free talc, lung cancer and mesothelioma in a cohort of talc miners and millers from Val Chisone, Italy); Wergeland et al., *Morbidity and Mortality in Talc-Exposed Workers*, 17 AM. J. INDUS. MED. 505 (1990) (finding no elevated incidence of lung cancer or mesothelioma in a cohort of 94 talc miners and 295 talc millers).

238 NCI 2021 PDQ at 14 (rejecting association between use of anti-inflammatory drugs and reduced risk of ovarian cancer); Bonovas et al., *Do nonsteroidal anti-inflammatory drugs affect the risk of developing ovarian cancer? A meta-analysis*, 60(2) BR J. CLIN PHARMACOL. 194, 197 (2005) (Ex. 38) (RR 0.93 (95% CI: 0.81-1.06) for aspirin use; RR 0.88 (95% CI: 0.76-1.01) for NSAID use).

239 Malmberg et al., *Serous tubal intraepithelial carcinoma, chronic fallopian tube injury, and serous carcinoma development*, 468(6) VIRCHOWS ARCH. 707, 712 (2016) (explaining that the study "aimed to see if histological signs of inflammation could be associated with ovarian carcinoma and precursor lesions" and that "no significant correlation was made between serous carcinoma and histological signs of inflammation or chronic tubal injury.").

240 Keskin et al., *Does Long-Term Talc Exposure Have a Carcinogenic Effect on the Female Genital System of Rats? An experimental pilot study*, 280 ARCHIVES GYNECOL. OBSTET. 925 (2009); Hamilton et al., *Effects of talc on the rat ovary*, 65(1) BR. J. EXP PATHOL. 101 (1984).

In sum, plaintiffs' evidence suggesting a plausible biological mechanism does not show that *externally* applied talc can migrate to the ovaries. Nor does it show that, if talc could reach the ovaries, that it is capable of causing cancer. And, even if cosmetic talc could travel up the reproductive tract *and* cause cancer, logically, one would expect to see an excess of cancers in tissues closer to the opening of the reproductive tract where, theoretically, there would be a higher concentration of such cosmetic talc. But that is not the case.

4. The "Toxic Soup" Theory

In an attempt to push back against the weight of scientific evidence, plaintiff experts have expanded their speculative theories on how Johnson's Baby Powder could cause ovarian cancer. One such theory is to point to evidence allegedly showing that talcum powder products could be contaminated with asbestos, "fibrous talc," and heavy metals, also known as the "toxic soup" theory. This theory asserts that talc contains harmful contaminants including asbestos and heavy metals, any or all of which can cause ovarian cancer. Plaintiffs in these cases allege both that (i) the talc itself causes cancer and (ii) exposure to even trace amounts of its alleged constituents can increase the risk of ovarian cancer.[241]

To advance their theory that the alleged contamination of Old JJCI's talc products with asbestos can cause ovarian cancer, plaintiffs rely on the 2012 IARC Monograph (the "IARC Asbestos Monograph")[242] regarding the health effects of asbestos (as well as "fibrous talc"). However, this monograph, as it relates to ovarian cancer, is premised on studies involving

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241 *See, e.g.*, 11/16/2018 Expert Report of Dr. Laura M. Plunkett, Ph.D., DABT in *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs. & Prods. Liab. Litig.*, (D.N.J. MDL No. 16-2738 (FLW) (LHG)), Dkt. 9740-27 ("Plunkett Rep.") at §§ IV, VII; 11/16/2018 Expert Report of Dr. Arch Carson, M.D., Ph.D. in *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs. & Prods. Liability Litig.,* (D.N.J. MDL No. 16-2738 (FLW) (LHG)), Dkt. 9740-8 ("Carson Rep.") at 3-8.

242 *See* World Health Org., IARC, *Asbestos (Chrysotile, Amosite, Crocidolite, Tremolite, Actinolite, and Anthophyllite)*, 100C IARC Monographs 219 (2012).

occupational asbestos exposure—women who worked directly with pure asbestos all day, every day at their jobs, for years at a time.[243] In particular, the IARC Asbestos Monograph was explicitly based "on five strongly positive cohort mortality studies of women with heavy occupational exposure to asbestos."[244] For example, one study involved women who manufactured asbestos-containing gas masks during World War II.[245] Such exposure is clearly incomparable to brief, daily applications of cosmetic talcum powder, even if one were to assume some asbestos contamination of the product (which J&J and Old JJCI have strongly denied). In addition, the occupational studies described in the IARC Asbestos Monograph primarily examined exposure to crocidolite asbestos[246]—a type of asbestos fiber that is not alleged to be a contaminant of talc. Moreover, there is no data showing that exposure to asbestos at non-occupational levels is associated with ovarian cancer. Indeed, environmental studies that have considered non-occupational exposure scenarios—*e.g.*, cohabitation with asbestos factory workers, or residency in an asbestos mining town—uniformly fail to find a statistically significant association with ovarian cancer.[247] Finally, the IARC Asbestos Monograph's finding

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243 *Id*. at 253-56.

244 *Id.* at 256.

245 Acheson et al., *Mortality of Two Groups of Women Who Manufactured Gas Masks from Chrysotile and Crocidolite Asbestos: A 40-Year Follow-Up*, 39 BR. J. INDUS. MED. 344 (1982) (cited in IARC Asbestos Monograph at 254).

246 IARC Asbestos Monograph at 253-56 (citing to Acheson 1982; Wignall & Fox, *Mortality of Female Gas Mask Assemblers*, 39 BR. J. IND. MED. 34 (1982); Reid et al., *The Mortality of Women Exposed Environmentally and Domestically to Blue Asbestos at Wittenoom, Western Australia*, 65 OCCUPATIONAL ENV'T MED. 743 (2008) ("Reid 2008"); Reid et al., *Gynecologic and Breast Cancers in Women After Exposure to Blue Asbestos in Wittenoom*, 18 CANCER EPIDEMIOLOGY BIOMARKETS PREV. 140 (2009) ("Reid 2009"); Pira et al., *Cancer Mortality in a Cohort of Asbestos Textile Workers*, 92 BR. J. CANCER 580 (2005)).

247 *See* Reid 2009 at 144 tbl. 3; Reid 2008 at 747; Ferrante et al., *Cancer Mortality and Incidence of Mesothelioma in a Cohort of Wives of Asbestos Workers in Casale Monferrato, Italy*, 115 ENV'T HEALTH PERSPECTIVES 1401, 1402 tbl. 2 (2007); *see also* IARC Asbestos Monograph at 256 (noting non-occupational studies show "non-significant, increases in . . . ovarian cancer").

of a causal association between even heavy occupational asbestos exposure and ovarian cancer has been criticized given the possibility of misclassification of peritoneal mesotheliomas as ovarian cancers, that the statistical association is "weak and inconsistent," and the fact that "there have not been reliable biological explanations *in vitro* or *in vivo* to explain the development of ovarian cancer due to asbestos."[248]

Plaintiffs further allege that Johnson's Baby Powder contains various heavy metals sometimes found in very low levels in talcum powder, including chromium, cobalt, and nickel, among others, and that such heavy metals contribute to the product's purported carcinogenicity.[249] However, not a single published study has ever connected any of these minerals to ovarian cancer.[250] Moreover, none of plaintiffs' experts can identify either (i) a level of exposure to these minerals that would be necessary to cause cancer or any other harm or (ii) the level of exposure to which women using talc in their genital area would be exposed.[251]

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248 *See* Slomowitz, et al., *Asbestos and Ovarian Cancer: Examining the Historical Evidence*, INT'L J. GYNECOL CANCER 2021; 31:122, 126-127 (noting a high rate of misclassification of disease based on available pathology); *see also* Reid A, et al., *Does Exposure to Asbestos Cause Ovarian Cancer? A Systematic Literature Review and Meta-analysis*, CANCER EPIDEMIOL BIOMARKERS PREV 2011;20:1287-1295 (reporting a decrease to an insignificant relative risk between asbestos exposure and ovarian cancer after taking misclassification of disease into account and further suggesting that "the IARC decision to determine asbestos exposure as a cause of ovarian cancer was premature and not wholly supported by the evidence.").

249 *See, e.g.*, Plunkett Rep. at §§ IV, VII; Carson Rep. at 3-8.

250 April 27, 2020 MDL Order at 172, n. 39 (discussing heavy metals and stating plaintiffs' expert Dr. Carson admitted there are "no studies linking these specific metals to ovarian cancer.").

251 *See e.g.*, 1/19/2019 Dr. Arch I. Carson deposition testimony in *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs. & Prods. Liab. Litig.*, (D.N.J. MDL No. 16-2738 (FLW) (LHG)), Dkt. 9731-4 ("Carson Dep.") at 175:6-11, 176:5-10 (agreeing that he did not know the amounts of heavy metals in the products and that he did not assess a woman's exposure to heavy metals through use of talcum powder); 12/19/2018 Dr. Laura Plunkett deposition testimony in *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs. & Prods. Liab. Litig.*, (D.N.J. MDL No. 16-2738 (FLW) (LHG)), Dkt. 9733-7 ("Plunkett Dep.") at 263:24-264:1 ("No, I have not done a – a calculation of a potential dose with perineal application for any of the heavy metals."); 2/4/2019 Dr. Daniel L. Clarke-Pearson deposition testimony in *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs. & Prods. Liability Litig.,* (D.N.J. MDL No. 16-2738 (FLW) (LHG)), Dkt. 9731-9 at 292:6-10 ("Q. How, if at all, did you factor the dose fragrances and heavy – or trace heavy metals into your analysis of the potential relationship between those compounds and ovarian cancer? A. I didn't factor in."); Plunkett Dep. at 263:12-264:3 (admitting that she

Indeed, plaintiffs' experts have conceded that some of these so-called heavy metals are present in food, drinking water, and vitamin supplements, as minerals vital to human health.[252] And, none of plaintiffs' experts has evidence suggesting that the levels of these heavy metals are higher in talc users as compared to non-users.

Undeterred, plaintiff experts also have implicated the fragrances that make up only about 0.22% (by weight) of Johnson's Baby Powder as a potential mechanism for causing ovarian cancer.[253] But, they cannot point to a single published human study linking any of the fragrances in J&J's/Old JJCI's talc products to ovarian cancer or even that the very minimal amount of fragrances in the products is capable of causing cancer. Nevertheless, plaintiff experts—with no support whatsoever—have asserted in filings across the country that exposure to even a *single molecule* of some of the fragrances used in J&J's/Old JJCI's talc products could lead to cancer.[254] This is, of course, a shocking claim that, if true, should have led to millions of cases of cancer around the world given the widespread use of these fragrances in many other products besides talcum powder.

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had done no analysis to determine the dose of chromium a woman would be exposed to "with perineal application").

252 Carson Dep. at 169:24-170:16.

253 *See* 2/25/2019 Expert Report of Dr. Nadia Moore, Ph.D. DABT, ERT in *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs. & Prods. Liability Litig.,* (D.N.J. MDL No. 16-2738 (FLW) (LHG)), Dkt. 9740-18 at 70-71, n.303 (citation omitted).

254 *See e.g.*, 5/29/2019 Plaintiffs' Steering Committee's Mem. In Response and Opp'n to J&J and JJCI's Mot. to Exclude Pls' Experts' Opinions Regarding Alleged Heavy Metals and Fragrances in Johnson's Baby Powder and Shower-to-Shower, *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs. & Prods. Liability Litig.,* (D.N.J. MDL No. 16-2738 (FLW) (LHG)), Dkt. 9885 at 60, n.222 (citing to 1/4/2019 Dr. Michael Crowley deposition testimony in *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs. & Prods. Liability Litig.,* (D.N.J. MDL No. 16-2738 (FLW) (LHG)), Dkt. 9733-11 at 131:22-132:3); *see also* 8/20/21 Pls' Combined Opp'n in Response to Defendants' Motions In Limine No. 5, *Giese v. Johnson & Johnson, et al.*, (Cir. Court, City of St. Louis, No. 1522-CC00419-02).

Multiple regulatory bodies and public health agencies have studied the well-developed body of scientific literature on whether perineal exposure to talc causes ovarian cancer but have not concluded that the scientific evidence establishes such a causal relationship.[255] In fact, each of the FDA, NCI, the American Cancer Society, NTP, IARC, and The American College of Obstetricians and Gynecologists have made public pronouncements and/or taken actions that are inconsistent with, and/or unsupportive of plaintiffs' claims that talc-based powder causes ovarian cancer.[256] Indeed, if talc use really caused ovarian cancer or mesothelioma, there would be a global epidemic of women getting such cancers. Fortunately, there is not.

5. The Ovarian Cancer MDL

Of the approximately 38,000 plaintiffs who have brought suit against J&J/Old JJCI on account of ovarian cancer claims, approximately 35,000 of those plaintiffs' suits are pending in the United States District Court for the District of New Jersey (the "MDL"). An MDL is a statutory vehicle whose purpose is "to avoid duplication of discovery, to prevent inconsistent pretrial rulings, and to conserve the resources of the parties, their counsel and the judiciary."[257]

Typically, an MDL is created near the inception of a mass tort litigation and, because it leads the way, tends to guide and help manage efficiencies across the entire litigation. In this

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255 As the sole outlier, Health Canada reached the conclusion that "[t]he available data are indicative of a causal effect." *See Screening Assessment Talc*, GOV'T OF CANADA (Apr. 22, 2021), *available at* https://www.canada.ca/en/environment-climate-change/services/evaluating-existing-substances/screening-assessment-talc.html#toc17.

256 *See* sections II.D & III B.3.c, *supra*; *see also* Am. Cancer Soc'y, *Talcum Powder and Cancer*, *available at* https://www.cancer.org/cancer/cancer-causes/talcum-powder-and-cancer.html (last updated Feb. 4, 2020) (stating that "[f]indings have been mixed" and that, while case-control studies have found small increased risk, these studies "can be biased"); *id.* ("It is not clear if consumer products containing talcum powder increase cancer risk."); Hal C. Lawrence, III, M.D., Exec. Vice President and CEO of the Am. Coll. of Obstetricians and Gynecologists, *Talc Use and Ovarian Cancer*, *available at* https://www.acog.org/news/news-releases/2017/09/talc-use-and-ovarian-cancer (Sep 11, 2017) ("There is no medical consensus that talcum powder causes ovarian cancer.").

257 *See* U.S. Judicial Panel on Multidistrict Litigation, *Overview of Panel, available at* https://www.jpml.uscourts.gov/overview-panel-0.

litigation, however, by the time the MDL was established, California and New Jersey formal state court consolidations had already been created, expert (Kemp) hearings had taken place in the New Jersey state consolidation and the court's opinion had been issued, and three trials had already occurred in St. Louis. Thus, the efficiencies expected across the litigation have not been fully realized. As a general matter, an overall lack of coordination between state court cases and the MDL has continued to this day. Furthermore, there is virtually no coordination between plaintiffs' counsel for the mesothelioma cases and those for the ovarian cancer cases, resulting in duplicity of burden and expense, particularly as it relates to discovery, including depositions of current and former employees.

Even so, J&J/Old JJCI have achieved certain key victories in the MDL. As part of its pretrial proceedings, in July 2019, the MDL court held *Daubert* hearings to determine whether certain general causation opinions of the parties' experts should be excluded for trial purposes. The court issued its decision in April 2020, leaving intact all of J&J's/Old JJCI's experts' opinions while restricting some of the plaintiffs' experts' general causation opinions.[258] While a clear referendum on certain of the flawed theories argued by plaintiff experts, these limitations on plaintiff expert opinions were not enough to prevent the MDL proceedings from continuing to move forward.

After the *Daubert* ruling, the MDL court ordered a two-stage "bellwether" process (*i.e.*, a subset of representative cases are identified for case-specific work-up and possibly trial, the outcomes of which can then be extrapolated across the litigation),[259] which began on June 4,

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258 *See* April 27, 2020 MDL Order.

259 Cases not selected for bellwether work-up remain inactive, ostensibly to later benefit from the bellwether analysis.

2020 with the MDL court's random selection of 1,000 cases from the 17,147 cases pending in the MDL as of May 1, 2020.[260] Those 1,000 plaintiffs were directed to provide medical records and to fill out authorizations and "Plaintiff Profile Forms," which provided certain background and medical information relevant to their cases.[261]

After selection, plaintiffs had the opportunity to have their cases removed from this case-specific evaluation by filing a statement with the court revoking waiver of their *Lexecon* rights.[262] 38 plaintiffs out of the 1,000 selected revoked waiver of *Lexecon*, thereby removing their cases from individual scrutiny. 15 additional plaintiffs did not proceed to the next stage for various reasons, including failure to submit the required documents described above. Of the remaining 947 plaintiffs, 30 plaintiffs (10 plaintiff-selected; 10 defense-selected; and 10 randomly-selected) were selected on September 18, 2020 to undergo further case-specific work-up.[263] Once selected, these 30 plaintiffs then had another opportunity to revoke waiver of *Lexecon* or dismiss their case with prejudice.[264] Cases removed from the group were replaced in the same manner in which they were originally chosen. Though none of the plaintiff-selected

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260 *See* 5/15/2020 Order in *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs. & Prods. Litig.*, (D.N.J. MDL No. 16-2738 (FLW) (LHG)), Dkt. 13317; 5/26/2020 Order in *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs. & Prods. Litig.*, (D.N.J. MDL No. 16-2738 (FLW) (LHG)), Dkt. 13428.

261 *See* 5/15/2020 Order in *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Practices . & Prods. Liability Litig.,* (D.N.J. MDL No. 16-2738 (FLW) (LHG)), Dkt. 13317.

262 In *Lexecon*, the U.S. Supreme Court held that an MDL court overseeing the pretrial work-up of a transferred case has no authority to reassign the case to itself for trial. *See Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26 (1998).

263 *See* 7/23/2020 Order in *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs. & Prods. Litig.*, (D.N.J. MDL No. 16-2738 (FLW) (LHG)), Dkt. 14108.

264 *See id.*

plaintiffs either revoked waiver of *Lexecon* or dismissed their cases,[265] 20 of the randomly-selected and defense-selected plaintiffs revoked waiver of *Lexecon* for, or dismissed their cases, thus removing those cases from individual scrutiny. This sweeping removal of cases from case-specific evaluation resulted in a seemingly endless series of case replacements.

Once the goals of the MDL ultimately have been achieved, that is, a determined amount of coordinated discovery and, potentially, completion of one or more bellwether trials, the MDL judge must seek remand of all pending cases back to the courts from which they were transferred.[266] Thus, after the MDL has disbanded, tens of thousands of cases will continue to proceed in courts across the country.

C. The Lack of Support for Mesothelioma Claims Caused by Talc

1. What is Mesothelioma?

Mesothelioma is a rare form of cancer that starts in cells in the linings of certain parts of the body. Of the over 325 million people in the United States, approximately 3,000-3,200 cases of mesothelioma develop annually.[267] Excess incidence of mesothelioma has been documented in association with certain occupations, such as those manufacturing amphibole asbestos products or working in settings with high exposures to amphibole asbestos-containing insulation.[268] Indeed, the rates of mesothelioma in the United States over time track the

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265 One of the plaintiffs who had initially revoked waiver of *Lexecon* in the first stage withdrew the revocation in the second stage after plaintiffs had already selected her so that she could remain as one of their 10 selected plaintiffs in the second stage.

266 *See* 28 U.S. C. § 1407(a) ("Each action so transferred shall be remanded by the panel at or before the conclusion of such pretrial proceedings to the district from which it was transferred unless it shall have been previously terminated….").

267 *See, e.g.,* SEER Data.

268 *See, e.g.*, Herbert Seidman, et al., *Mortality Experience of Amosite Asbestos Factory Workers: Dose-Response Relationships 5 to 40 Years After Onset of Short-Term Work Exposure*, 10 AM. J. INDUS. MED. 479 (1986); G. Berry, et al., *Mortality from all cancers of asbestos factory workers in east London 1933-80*, 57 OCCUPATIONAL ENV'T MED. 782 (2000).

commercial use of asbestos over time.[269] As the commercial use of asbestos increased, rates of mesothelioma in men increased a few decades later (the length of time it takes mesothelioma to develop after exposure to asbestos).[270] As the commercial use of asbestos decreased, rates of mesothelioma in men decreased as well.[271]

Mesothelioma is even rarer in women than in men. Only approximately 700 mesothelioma cases occur in women each year in the United States,[272] and those rates have remained constant over time.[273] Women tend not to have the same history of occupational exposure to asbestos (*i.e.*, generally speaking, women did not make up the primary populations of workers who mined asbestos, made asbestos-containing industrial products, or worked consistently with and around such products when asbestos use was prevalent). Thus, modern science has been critical in understanding the small but constant rate of mesothelioma in women, and indeed, in the ongoing occurrence of mesothelioma more generally.

It has become increasingly clear that not all mesothelioma is caused by exposure to asbestos. Rather, like other cancers, mesothelioma can occur naturally through random genetic mutations when cells replicate.[274] A cell's random mutation leads to a genetic error, which is then propagated as that cell divides and multiplies—ultimately causing and spreading cancer.[275] Developing science increasingly is recognizing the role of genetics in the development of

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269 Moolgavkar, et al., *Epidemiology of Mesothelioma* in ASBESTOS AND MESOTHELIOMA (Test, JR ed., 2017).

270 *Id.*

271 *Id.*

272 *See, e.g.,* SEER Data.

273 *Id.*

274 *See, e.g.*, Richard L. Attanoos, et al., *Malignant Mesothelioma and Its Non-Asbestos Causes*, 142 ARCH. PATHOL. LAB. MED. 753 (2018) ("Attanoos 2018").

275 *See, e.g.*, Tomasetti C, Li L, Vogelstein B., *Stem cell divisions, somatic mutations, cancer etiology, and cancer prevention*, SCIENCE 355(6331):1330-1334 (2017).

mesothelioma. Numerous genetic mechanisms have been implicated including germline BRCA1 associated protein-1 (BAP-1) inactivation syndrome, structural gene rearrangements in Ewing sarcoma breakpoint region 1 (EWSR1) or fused in sarcoma (FUS), and anaplastic lymphoma kinase (ALK) rearrangements.[276]

Studies show that approximately 50-75% of mesothelioma in women is naturally occurring and not a result of asbestos exposure.[277] Just last year, doctors from MD Anderson published a case series on 164 female patients with peritoneal mesothelioma (mesothelioma in the lining of the stomach). Of the 122 patients where asbestos exposure could be assessed, only 11 (9%) had a history of direct or indirect exposure to asbestos.[278] Notably, no talc use was documented among *any* of the 122 patients.[279]

Notwithstanding the well-established body of science associating mesothelioma with extensive exposure to asbestos and the developing body of science regarding naturally occurring mesothelioma, litigation alleging that sub-trace amounts of asbestos, if any, in talcum powder products caused mesothelioma is suddenly booming.

2. Plaintiffs Cannot Reasonably Establish Causation

In mesothelioma cases, there is not the same sort of debate concerning general causation as occurs in the ovarian cancer cases. The epidemiological evidence does not suggest that

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276 *See, e.g.,* Hung, et al., *Identification of ALK Rearrangements in Malignant Peritoneal Mesothelioma*; 4(2) JAMA ONCOLOGY, 235-254, (2018); Argani, et al., *Pediatric Mesothelioma With ALK Fusions A Molecular and Pathologic Study of 5 Cases*; 45(5) AJSP 653 (2021); Murumagi, A., *STRN-ALK rearranged pediatric malignant peritoneal mesothelioma - Functional testing of 527 cancer drugs in patient-derived cancer cells*, 14(4) TRANSLATIONAL ONCOLOGY 101027 (2021); Miyagawa, C., et al., *A Novel Malignant Peritoneal Mesothelioma with STRN Exon 2 and ALK Exon 20: A Case Report and Literature Review*, THE ONCOLOGIST, 25:1-6 (2021).

277 Attanoos 2018; Spirtas R, Heineman EF, Bernstein L, et al., *Malignant mesothelioma: attributable risk of asbestos exposure,* OCCUPATIONAL AND ENV'T MED. 1994; 51:804-811.

278 Malpica, et al., *Malignant Mesothelioma of the Peritoneum in Women: A Clinicopathologic Study of 164 Cases*, 45(1) AM. J. SURGICAL PATHOL. 45 (2021).

279 *Id*. at 47.

cosmetic talc generally causes mesothelioma, and, in contrast to their assertions regarding ovarian cancer, plaintiffs largely do not claim that exposure to unadulterated talc generally causes mesothelioma. At the same time, the parties do not dispute that exposure to sufficient levels of inhaled asbestos can cause mesothelioma. Instead, the critical question for causation purposes is whether an individual plaintiff can prove that she was exposed to sufficient levels of asbestos via her use of J&J's/Old JJCI's talcum powder products to cause mesothelioma.

In all or most mesothelioma cases, plaintiffs argue that the individual plaintiff was exposed to talcum powder that contained asbestos, but often do so without physical evidence of talcum powder *actually used* by plaintiffs themselves. Without any direct evidence of exposure to asbestos-containing talcum powder, many mesothelioma plaintiffs pursue a strategy of "extrapolation." First, they attempt to prove that some talcum powder products are contaminated with "trace" amounts of asbestos. Then, plaintiffs proffer experts who purport to estimate the cumulative exposure to asbestos that they allegedly experienced as a consequence of such product usage. Plaintiffs' experts then opine that the plaintiff was exposed to a level of asbestos over time that is sufficient to have caused mesothelioma.

This approach does not provide competent evidence that J&J's/Old JJCI's talcum powder products can cause or have caused mesothelioma. As detailed in section II.F, J&J/Old JJCI have subjected the cosmetic talc to be used in their products to regular, routine testing, as well as confirmatory testing by outside experts, for decades, which testing has consistently failed to detect asbestos in their cosmetic talc. Moreover, because plaintiffs' "extrapolation" approach relies on samples of talc admittedly never used by the plaintiff herself, such tests cannot establish that any given plaintiff was exposed to any asbestos, let alone levels of asbestos sufficient to cause mesothelioma.

3. The Epidemiological Evidence Does Not Show an Association Between Use of Talcum Powder Products and Mesothelioma.

Epidemiology is considered the "gold standard" for establishing a causal association between exposure to an alleged agent and a disease. While there are a number of epidemiological studies, and quite a bit of scientific debate, concerning whether there is an association between perineal use of cosmetic talc and ovarian cancer, the Debtor is not aware of any similar studies that have examined incidence of mesothelioma in cosmetic talc users.[280]

Indeed, the few studies that do exist—albeit concerning high dose, occupational exposure to talc (*i.e.,* exposure above that of the typical user of cosmetic products)—tend to show that talc does not increase the risk of mesothelioma. For example, a 1976 study looked at mortality rates among male workers in talc mines and mills in the Germanasca and Chisone valleys in Italy between 1921 and 1950.[281] That study found no cases of mesothelioma among the workers.[282] A 1979 study looked at miners and millers in the same region but looked at workers from 1946 to 1974 and similarly found no cases of mesothelioma among the workers.[283] Three subsequent updates to the 1979 study, the most recent in 2021, confirmed that there have been no cases of

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280 The Debtor is aware of two studies published by plaintiffs' expert witnesses that discuss patients with mesothelioma who were evaluated as part of a "medical-legal evaluation." Moline, J., et al., *Mesothelioma Associated With the Use of Cosmetic Talc*, JOEM 62:1, 11-17. (2020) ("Moline 2020"); Emory, T., et al., *Malignant mesothelioma following repeated exposures to cosmetic talc: A case series of 75 patients*; AM J INDUS. MED. (2020) ("Emory 2020"). Such case studies are not the product of impartial research by disinterested researchers and are not probative to the question at hand.

281 Giovani F. Rubino et al., *Mortality Study of Talc Miners and Millers*, 18 J OCCUPATIONAL MED. 187 (1976).

282 *Id.*

283 Giovani F. Rubino et al., *Mortality and Morbidity Among Talc Miners and Millers in Italy*, *in* DUSTS AND DISEASE, PROCEEDINGS OF THE CONFERENCE ON OCCUPATIONAL EXPOSURES TO FIBROUS AND PARTICULATE DUST AND THEIR EXTENSION INTO THE ENVIRONMENT 357-363 (Richard Lemen & John M. Dement eds., Pathotox Publisher, Inc.) (1979).

mesothelioma among the workers studied.[284] In 1979, NIOSH-Harvard published a study on the effects of occupational exposure to talc not contaminated with asbestos among 392 miners and millers in Vermont.[285] Although that study found higher mortality rates "due to non-malignant respiratory disease" among the millers (but not the miners), the study found no cases of mesothelioma.[286] A 2019 update included a review of available death certificates of the workers in an expanded version of that cohort, and attributed one death to mesothelioma.[287] The study noted the possibility that the worker—whose death certificate specifically noted exposure to asbestos—had been exposed to asbestos "in other occupations" and/or "ionizing radiation."[288] At any rate, the inclusion of that worker still did not result in a statistically significant elevated risk of mesothelioma in the cohort, and the study concluded that "there is no evidence of increased risk of respiratory cancer."[289] In 2020, a pooled cohort study of talc miners and millers in Austria, France, Italy, Norway, and Vermont found no cases of mesothelioma, concluding that "the epidemiological evidence from cosmetic talc miner/miller cohort studies does not support a hypothesis that cosmetic talc exposures are associated with increased risk of pleural mesothelioma."[290]

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284 Maurizio Coggiola et al., *An Update of a Mortality Study of Talc Miners and Millers in Italy*, 44 AM. J. INDUS. MED. 63 (2003); Pira 2018; Ciocan, C., et al., *Mortality in the cohort of talc miners and millers from Val Chisone, Northern Italy: 74 years of follow-up*, ENV'T RES. 203 (2021).

285 Selevan SG, Dement JM, Wagoner JK, Froines JR. 1979a. *Mortality patterns among miners and millers of non-asbestiform talc: Preliminary report*, J. ENV'T PATHOL. 2:273–84 (1979).

286 *Id.*

287 Fordyce, Leonhard, Mowat & Moolgavkar, *A 37-year Update on Morality Patterns in an Expanded Cohort of Vermont Talc Miners and Millers,* 61:11 J. OCCUPATIONAL & ENV'TL MED 916 (2019).

288 *Id.* at 922.

289 *Id*. at 923; *see also* Fordyce, T., et al., *Response to Letter to the Editor: Misrepresentation by Egilman et al., of the Fordyce et al., (2019) Vermont Talc Miners and Millers cohort study update*, 62(1) J. OCCUPATIONAL & ENV'T MED. 19 (2020).

290 Ierardi, MA, et al., *Absence of Mesothelioma Risk Maintained in an Expanded International Cohort of Cosmetic Talc Miners and Millers*, INHALATION TOXICOL., 32(6):257-264 (2020). Finding "no consistent

4. Plaintiffs' Non-Epidemiological Evidence Does Not Prove that Talcum Powder Products Are Contaminated With Asbestos.

Plaintiffs dismiss the lack of studies linking talc to mesothelioma, asserting instead that it "has been established epidemiologically that breathing in asbestos causes mesothelioma."[291] That assertion is only relevant if, among other things, the talcum powder products are contaminated with asbestos.

a. Dr. Longo's Testing and Testimony Do Not Prove that J&J's/Old JJCI's Talcum Powder Products Are Contaminated with Asbestos.

Plaintiffs do not contend that all talcum powder products contain asbestos. Rather, plaintiffs introduce evidence, typically through Dr. William Longo, that some products have been contaminated with asbestos.

(1) Who is Dr. William Longo?

Dr. Longo is plaintiffs' primary expert in talc litigation. Over the past 30 years, Dr. Longo has testified in 2,500 to 3,000 depositions.[292] Dr. Longo has testified at least once a week, every week, in recent years.[293] He recently testified that, 95% of the time that he is in court, Dr. Longo is testifying for plaintiffs' in asbestos litigation[294] and that 100% of his work in talc

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pattern" in those studies, the IARC 2010 Monograph concluded that "there was inadequate evidence from epidemiological studies to assess whether inhaled talc not containing asbestos or asbestiform fibres [sic] causes cancer in humans." *See* IARC 2010 Monograph at 412.

291 8/9/2019 Plaintiffs' Memorandum of Law in Opposition to Defendants Motion to Set Aside Verdict or, In the Alternative, for a New Trial or Remittitur, *Olson v. Brenntag N.A., Inc*., (N.Y. Sup. Ct., No. 190328/2017 (GL)) at 24.

292 5/31/2018 Dr. William Longo trial testimony in *Brick v. Brenntag North America, Inc., et al.*, (Super. Ct. Ca., L.A. Cnty., No. JCCP 4674/BC674595) at 171:20-22.

293 10/19/2018 Dr. William Longo trial testimony in *Allen v. Brenntag North America, Inc., et al.*, (Super. Ct. Ca., Humboldt Cnty., No. DR 180132) at 3519:10-13.

294 7/23/2019 Dr. William Longo trial testimony in *Hayes v. Colgate-Palmolive Co., et al.*, (Jefferson Cir. Ct., Ky., No. 16-CI-03503) at 117:17-20.

litigation to-date has been on behalf of plaintiffs.[295] Indeed, Dr. Longo has testified that he believes that ***every*** plaintiffs' attorney in the country discloses him in all of their asbestos lawsuits.[296] In other words, everyone knows what Dr. Longo will say, before you even have to ask him.

Dr. Longo is the President and a 75% owner of his lab Material Analytical Services, LLC ("MAS").[297] Dr. Longo has testified that MAS has billed over $30 million for legal work on behalf of plaintiffs in the last 30-plus years[298] and that working for plaintiffs in litigation has allowed his lab to survive.[299] MAS has billed at least $2.5 million for work supporting talc litigation against J&J/Old JJCI.

However prolific his presence in the talc litigation, courts have excluded Dr. Longo's opinions on numerous occasions.[300] One court has described Dr. Longo's work as "junk science"—concluding that studying "Dr. Longo's testimony reveal[ed] it to be practiced and to

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295 2/26/2019 Dr. William Longo trial testimony in *Olson et al. v. Brenntag North America, Inc., et al.,* (Supr. Ct. N.Y., N.Y. Cnty., No. 190328/2017) at 1646:24-1647:2.

296 2/7/2019 Dr. William Longo trial testimony in *Leavitt et al. v. Johnson & Johnson, et al.,* (Super. Ct. Ca., Alameda Cnty., No. RG17882401) at 179:3-7.

297 7/23/2019 Dr. William Longo trial testimony in *Hayes v. Colgate-Palmolive Co., et al.,* (Jefferson Cir. Ct., Ky., No. 16-CI-03503) at 114:14-18.

298 *Id.* at 118:6-10.

299 3/5/2019 Dr. William Longo trial testimony in *Rimondi et al. v. BASF Catalysts LLC, et al.*, (Super. Ct. N.J., Middlesex Cnty., No. MID-2912-17-AS) at 35:25-36:14.

300 *See, e.g.*, 7/23/2018 Order in *Weirick v. Brenntag N. Am., Inc.*, (Super. Ct. Ca., Alameda Cnty., No. BC656425) at 27-41; 10/1/2018 trial transcript in *Allen v. Brenntag N. Am., Inc.*, (Cal. Super. Ct., No. DR 180132) at 886:18-893:25; 7/5/2001 Order in *In re Lamar Cty. Asbestos Litig.*, (Tex. Dist. Ct., No. 2000-3559) (calling Dr. Longo's MAS tests "junk science"); *Krik v. Crane Co.*, 71 F. Supp. 3d 784, 790 (N.D. Ill. 2014); *Suoja v. Owens-Ill., Inc.*, No. 05-CV-219-BBC, 2015 WL 2341436, at *3 (W.D. Wis. May 14, 2015); *In re Welding Fume Prods. Liab. Litig.*, No. 1:03-CV-17000, 2010 WL 7699456, at *76 (N.D. Ohio June 4, 2010); *In re Garlock Sealing Techs., LLC*, 504 B.R. 71, 80 (Bankr. W.D.N.C. 2014) (finding Dr. Longo's studies "pseudo-science at best"); *Dugas v. 3M Co.*, No. 3:14-CV-1096-J-39JBT, 2016 WL 3946802, at *6 (M.D. Fla. June 21, 2016); *Tyre v. CSC Transp., Inc.*, No. 16-2002-CA-4837, 2003 WL 26474173, at *1-4 (Fla. Cir. Ct. Sept. 24, 2003); *Ball v. Consol. Rail Corp.*, 142 Ohio App. 3d 748, 758-59, 756 N.E.2d 1280, 1288 (Ohio App. 2001); *Grigg v. Allied Packing & Supply Inc.*, No. RG12 629580, 2013 WL 8103870, at *2 (Cal. Super. Ct. Mar. 12, 2013); *In re Asbestos Pers. Injury Litig.*, No. 03-C-9600, 2009 WL 10696863, at *5 (W. Va. Cir. Ct. Feb. 20, 2009).

employ misdirection and evasiveness. It is at best disingenuous, not credible and unsupported by any respectable community of scientists."[301] Another court called his work "pseudo-science at best" and pointed out that "Dr. Longo's studies were carried out in such a way as to produce the highest results possible and to overdramatize the process."[302]

Dr. Longo also has given inaccurate testimony concerning his laboratory's history of testing cosmetic talcum powder. On at least ***ten*** occasions in cosmetic talcum powder litigation against J&J/Old JJCI, Dr. Longo testified under oath that his laboratory never tested cosmetic talcum powder for the presence of asbestos before he was retained in late 2016.[303] This testimony was incorrect. After a laborious investigation into years of deposition transcripts, defense counsel discovered that, in 2002, Dr. Longo testified in a traditional asbestos case: "[W]e have done our own studies on talc, but what I haven't been able to do is find a cosmetic where I can say, yes, that has asbestos in it."[304] He further testified that he was "very familiar" with the issue and that cosmetic talc containing asbestos was "an urban legend."[305] In short, Dr. Longo testified, "[w]e've looked. We have not found it."[306] In another transcript uncovered by defense counsel, six years before being retained in talc litigation, in 2010, Dr. Longo testified that if talc is not sourced from New York (and J&J/Old JJCI never sourced talc from New York), then "that

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301 7/5/2001 Order in *In re Lamar Cty. Asbestos Litig.*, (Tex. Dist. Ct., No. 2000-3559), Ex. A at 1.

302 *In re Garlock Sealing Techs., LLC*, 504 B.R. at 80.

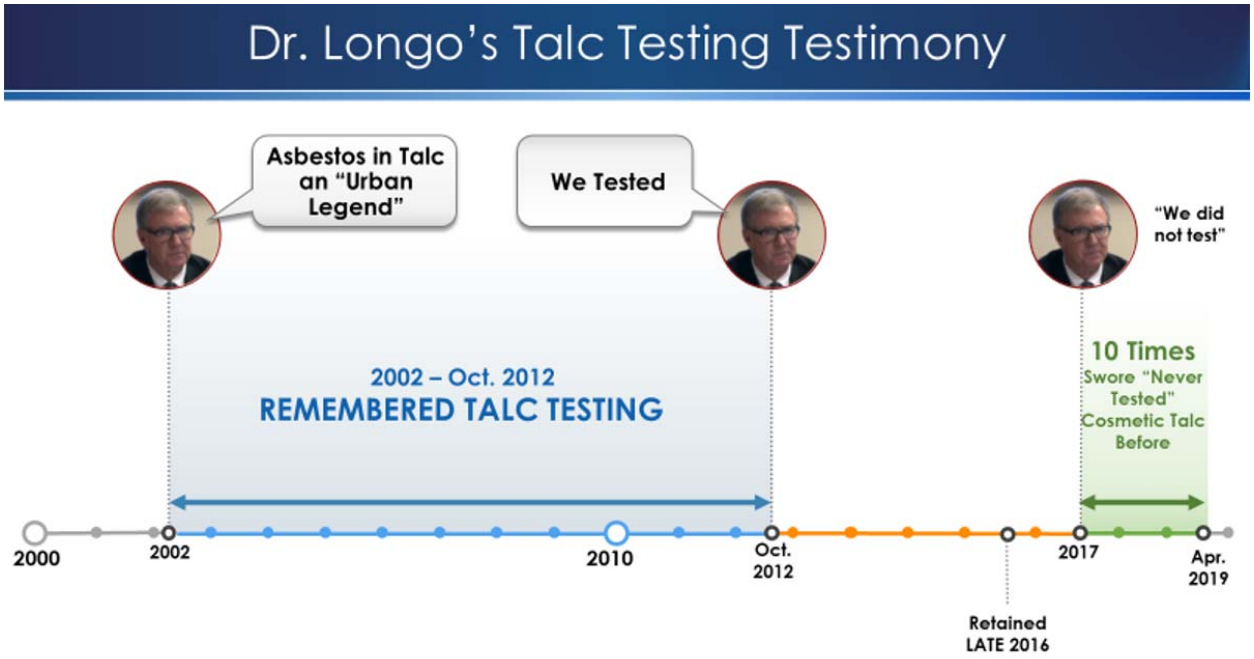
303 2/26/2019 Dr. William Longo trial testimony in *Olson et al. v. Brenntag North America, Inc., et al.*, (Supr. Ct. N.Y., N.Y. Cnty., No. 190328/2017) at 1646:6-23; 10/2/2019 Dr. William Longo trial testimony in *Crudge et al. v. Johnson & Johnson, et al.*, (Super. Ct. Ca., L.A. Cnty., No. BC685901) at 232:3-6.

304 7/18/2002 Dr. William Longo deposition testimony in *Starkweather v. ACandS, Inc., et al.*, (Mass. Super. Ct., No. 00-6030) at 155:20-23.

305 *Id.* at 155:10-17.

306 5/28/2002 Dr. William Longo deposition testimony in *Manbodh v. Hess Oil Virgin Islands Corp., et al.,* (V.I. Terr. Ct., No. 324/1997) at 106:11-19.

talc is clean,"[307] the implication being that Dr. Longo had performed some form of analysis to confirm the veracity of his testimony. And, in 2012, Dr. Longo testified that MAS had performed in-house studies assessing cosmetic talc.[308] Dr. Longo's excuse for the ten instances of incorrect testimony is that he simply "forgot" everything about the talc testing performed by his laboratory by the time that he began testifying against J&J/Old JJCI in 2017.[309] A depiction of Dr. Longo's inaccurate testimony regarding talc testing is set forth below.



(2) Dr. Longo's Allegations that J&J/Old JJCI Talcum Powder Contains Asbestos

In reports dated August 2017 and March 2018, Dr. Longo claims to have tested 32 samples of J&J/Old JJCI talcum powder products dating back to the 1950s, finding "trace"

307 10/29/2010 Dr. William Longo deposition testimony in *Edwards et al. v. ACandS, Inc., et al.,* (Cir. Ct. Md., Baltimore City, No. 24X08000416) at 102:19-103:11.

308 10/1/2012 Dr. William Longo deposition testimony in *Dean et al. v. ACandS, Inc., et al.*, (Cir. Ct. Md., Baltimore City, No. 24X10000415) at 37:20-38:16.

309 7/23/2019 Dr. William Longo trial testimony in *Hayes v. Colgate-Palmolive Co., et al.,* (Jefferson Cir. Ct., Ky., No. 16-CI-03503) at 125:1-5; 271:8-272:12.

amounts of asbestos in 18 of those samples (56%).[310] Subsequently, Dr. Longo claims to have tested another 72 samples—57 from J&J/Old JJCI talcum powder products, and 15 historical samples provided by Old JJCI's talc supplier, Imerys[311] that Dr. Longo claims to "represent[] talc that was used in Johnson & Johnson talc products," including talc sourced from Vermont, Italy, and Korean mines—finding "trace" asbestos in 50 (69%) of the samples.[312] Dr. Longo claims that his laboratory has "issued reports for the testing of approximately 118 containers of J&J/Old JJCI talc products (primarily Jonson's Baby Powder) that cover a span of decades," and has "identified and report on regulated asbestos in 78 of 118 containers of Johnsons' Baby Powder and Shower to Shower, or 66% of the total amount of J&J/Old JJCI talc products reported on to date."[313]

Dr. Longo's purported findings of asbestos are erroneous or otherwise unreliable. Many if not most of the 18 initial samples that tested positive came from bottles sourced from anonymous eBay sellers, purported "collectors," and the father of a lawyer representing plaintiffs.[314] Some had sat unsealed and opened, under unknown circumstances, for years or decades,[315] and contained other contaminants not found alongside talc in nature such as

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310 *See, e.g.,* Expert Report of Dr. William Longo and Dr. Mark Rigler "Analysis of Johnson & Johnson Baby Powder and Valiant [sp] Shower to Shower Talc Products for Amphibole (Tremolite) Asbestos" (Aug. 2, 2017) ("Longo Aug. 2, 2017 Rep.").

311 In February 2019, Old JJCI's talc supplier, Imerys Talc America, Inc. and two of its affiliates, Imerys Talc Vermont, Inc. and Imerys Talc Canada, Inc. (collectively, "Imerys") filed voluntary petitions under chapter 11 of the Bankruptcy Code in the United States Bankruptcy Court for the District of Delaware (the "Imerys Bankruptcy"). Imerys has potential liability for personal injury claims arising from exposure to talc it sold to customers, including Old JJCI. The First Day Declaration contains a discussion of the Imerys Bankruptcy.

312 *See id.*

313 Declaration of William E. Longo, Ph.D., dated May 11, 2020 at 1-2.

314 *Id.*

315 *See e.g.*, 10/19/2018 Dr. William Longo trial testimony in *Allen v. Brenntag North America, Inc., et al.* (Super. Ct. Ca., Humboldt Cnty., No. DR 180132) at 3604:20-22; 2/26/2019 Dr. William Longo trial

diatomaceous earth.[316] And Dr. Longo has conceded that "the opening in a bottle gives plenty of room" for it to be contaminated with "[ambient] asbestos fiber[s]."[317] Indeed, at least one state court has excluded portions of Dr. Longo's testing on the grounds that plaintiffs failed to make an adequate "chain of custody" showing.[318]

In addition, although Dr. Longo claims to have tested J&J's/Old JJCI's talc with TEM and PLM, there are significant problems in Dr. Longo's selection and in the application of the methodologies that he claims to use. As an example, on April 27, 2020, Judge Wolfson issued a wide-ranging *Daubert* opinion in the MDL proceedings that excluded certain aspects of Dr. Longo's testing—specifically his PLM analyses—on the basis that they were not sufficiently reliable.[319]

Dr. Longo's choice to use PLM for testing talc in the MDL proceedings came as a surprise given that he has long distanced himself from that method for testing talc. Dr. Longo has never "personally analyzed a sample for the presence of asbestos using PLM."[320] As he put it: "I don't do PLM analysis."[321] Dr. Longo previously testified that "the PLM method is not

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testimony in *Olson et al. v. Brenntag North America, Inc., et al.*, (Supr. Ct. N.Y., N.Y. Cnty., No. 190328/2017) at 1739:17-21.

316 4/22/2019 Dr. Matthew Sanchez trial testimony in *Olson et al. v. Brenntag North America, Inc., et al.* (Supr. Ct. N.Y., N.Y. Cnty., No. 190328/2017) at 6488:16-6491:22 (discussing identification of diatomaceous earth in container that Dr. Longo used for the "Below the Waist" study).

317 2/26/2019 Dr. William Longo trial testimony in *Olson et al. v. Brenntag North America, Inc., et al.* (Supr. Ct. N.Y., N.Y. Cnty., No. 190328/2017) at 1739:6-12.

318 *See* 7/23/2018 Order in *Weirick v. Brenntag N. Am., Inc.*, (Cal. Super. Ct. L.A. Cty., No. BC656425) at 27-35.

319 April 27, 2020 MDL Order at 56-57.

320 1/25/2019 Dr. William Longo deposition testimony in *Yvette Young v. Johnson & Johnson et al.,* (Mo. Cir. Ct., St. Louis City, No. 1522-CC09728-02) at 85:18-20.

321 *Id.* at 86:5-6.

appropriate to do an evaluation for these types of products—*i.e.*, talcum powder products.[322] He has testified that "[t]he concentration is too low and you're dealing with small fibrous structures and it's going to be beyond the resolution of the PLM."[323] He has testified that, when trying to determine whether asbestos is present in talc, "TEM is the only method to determine that."[324]

Despite Dr. Longo's long history of criticizing PLM for testing talc, he had analysts at his laboratory perform PLM analyses as part of his laboratory's testing of historic containers of J&J/Old JJCI talcum powder products.[325] Dr. Longo claimed that those analyses identified ultra-trace levels of asbestos (<0.01%).[326] But this testing failed to survive a *Daubert* challenge. In excluding Dr. Longo's PLM analyses from the MDL proceedings, Judge Wolfson contrasted Dr. Longo's prior testimony about the limitations of PLM with the fact that he now purports to find asbestos at ultra-trace levels that he had previously said could not be achieved using this method.[327]

Notwithstanding the exclusion of his PLM analyses by Judge Wolfson, Dr. Longo continues to use PLM methods for testing J&J's/Old JJCI's talc.

Further, Dr. Longo has declined to disclose internal reference charts used by his analysts to determine visually how much asbestos was in a PLM sample, without which his results cannot

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322 8/24/2018 Dr. William Longo trial testimony in *Weirick et al. v. Brenntag North America, Inc., et al.,* (Super. Ct. Ca., L.A. Cnty., No. BC656425) at 2921:25-28.

323 4/17/2018 Dr. William Longo deposition testimony in *Weirick et al. v. Brenntag North America, Inc., et al.*, (Super. Ct. Ca., L.A. Cnty., No. BC656425) at 283:5-7.

324 11/20/2017 Dr. William Longo deposition testimony in *Wittman v. Brenntag North America Inc., et al.*, (Super. Ct. Ca., L.A. Cnty., No. BC646439) at 203:12-13.

325 *See, e.g.,* Longo Aug. 2, 2017 Rep.

326 *Id.*

327 April 27, 2020 MDL Order at 54-55.

be reproduced or verified.[328] Indeed, given these critical flaws, it is unsurprising that efforts by a third-party lab engaged by Dr. Longo to verify his results found significant inconsistencies, underscoring, as Judge Wolfson held in the MDL, "the very real reliability and reproducibility issues plaguing Dr. Longo's PLM testing."[329] Dr. Longo has also used sample preparation techniques such as his "Blount PLM method"[330] which has not been validated or accepted by any regulatory organization.

J&J's/Old JJCI's experts from RJ Lee Group, including Dr. Matthew Sanchez, have used XRD, PLM, and TEM to test historic samples of talcum powder products that Dr. Longo reported testing. Dr. Sanchez has stated that he has not found asbestos in any of the containers from J&J's historic archive and has opined that the amphibole structures that Dr. Longo claims to be detecting are in actuality non-asbestiform particles.[331] In fact, when RJ Lee Group and Dr. Longo analyze the same samples, RJ Lee Group identifies amphibole minerals more often than Dr. Longo (the amphibole minerals identified by RJ Lee Group have been non-asbestiform),[332] a discrepancy that suggests that Dr. Longo's preparation techniques do not explain his anomalous "asbestos" findings because other laboratories are entirely capable of seeing the same particles that Dr. Longo is calling "asbestos."

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328 Judge Wolfson held that "[w]ithout that information, which is internally created by [Dr. Longo's lab], reproducing Dr. Longo's test under the PLM would not be possible, and hence, the testing is unreliable." April 27, 2020 MDL Order at 155.

329 *Id*.

330 Declaration of William E. Longo, Ph.D., dated May 11, 2020 at 1-2.

331 *See e.g.*, 8/2/2021 Dr. Matthew Sanchez trial testimony in *Prudencio v. Johnson & Johnson, et al.*, (Super. Ct. Ca., Alameda Cnty., No. RG20061303) at 7938:21-7939:4.

332 *Id*.

5. Plaintiffs' Experts' Testimony, Based on Dr. Longo's Test Results and Other Purported Historical Evidence of Contamination, Does Not Prove that a Plaintiff was Exposed to Asbestos in J&J or Old JJCI Talcum Powder Products.

Dr. Longo's testing and testimony, standing alone, is insufficient to show that any particular plaintiff was exposed to asbestos in a J&J/Old JJCI talcum powder product.[333] Without evidence that an individual plaintiff actually purchased and used a contaminated talcum powder product, there is no direct evidence that plaintiff was exposed to any asbestos through such products. To fill this gap, plaintiffs in mesothelioma cases make a number of inferential leaps, typically via one or more causation experts, to extrapolate from Dr. Longo's findings of "trace" asbestos in some samples to the conclusion that a plaintiff must have been exposed to asbestos in J&J/Old JJCI talcum powder products.

First, plaintiffs' causation experts testify that mesothelioma is a "signal tumor," meaning someone with mesothelioma almost always got it from exposure to asbestos. Those experts also testify, based on a review of plaintiff's medical, occupational, and environmental history, that each plaintiff's mesothelioma was neither spontaneous nor caused by any alternative factors and they purport to "rule out" occupational and environmental asbestos exposure.[334]

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333 Indeed, in the MDL, Judge Wolfson found that Dr. Longo's purported findings of "ultra-trace" asbestos in some (but not all) talcum powder product samples, coupled with his failure to conduct any exposure analysis, cannot support a conclusion that "[J&J's/Old JJCI's] talc products causes exposure, let alone significant exposure, to asbestos." April 27, 2020 MDL Order at 157. As a result, Dr. Longo will not be permitted to testify in the MDL to "the likelihood that talc users were exposed to 'significant' amounts of asbestos, [or] indeed, any exposure [to asbestos]" via those products. *Id.*; *see also* 7/23/2018 Order in *Weirick v. Brenntag N. Am., Inc*., (Cal. Super. Ct. L.A. Cty., No. BC656425) at 27-35 (the California Superior Court has similarly excluded Dr. Longo's attempt to "extrapolate" from findings of "low levels" of asbestos in some talcum powder products, excluding his opinion that "individuals who used Johnson & Johnson's Baby Powder . . . would have, more likely than not, been exposed to fibrous amphibole asbestos.").

334 One of plaintiffs' experts has testified that he does not believe mesothelioma occurs spontaneously in the United States because "almost everyone in the United States has had exposure to asbestos." 3/11/2019 Dr. Murray Finkelstein trial testimony in *Olson et al. v. Brenntag North America, Inc., et al.*, (Supr. Ct. N.Y., N.Y. Cnty., No. 190328/2017) at 2796:1-19. Opinions such as these support plaintiffs' argument against spontaneous mesothelioma, but they directly undercut plaintiffs' assumption that a talc user who develops

The causation experts then rely on some combination of Dr. Longo's testing, a 1991 article claiming to find asbestos in a Sample "I" that the author later claimed was Johnson's Baby Powder,[335] and their own interpretation of historical documents that purportedly show that J&J's/Old JJCI's talc was contaminated with asbestos during the period plaintiff was using J&J/Old JJCI talcum powder products. Based on that evidence, plaintiffs' experts opine that it is highly likely that plaintiffs were exposed to significant levels of asbestos.[336]

Even assuming that Dr. Longo's findings are reliable (something the company and its own testing experts vigorously dispute), there is little credible basis to extrapolate from tests of a small number of samples of talc that a plaintiff never used (and a small handful of historical documents) to draw conclusions about the likelihood of contamination across all talcum powder products. This is particularly so in the face of the extensive routine and confirmatory testing regularly conducted by the company, its suppliers, and independent third parties over the past 50 years, which have not shown such contamination.[337]

6. Plaintiffs' Evidence is Insufficient to Show that Any Plaintiff Was Exposed to Levels of Asbestos Sufficient To Cause Mesothelioma.

Plaintiffs' causation experts for the most part acknowledge that it is not sufficient merely to show "any" exposure to asbestos to establish causation. Indeed, certain of those experts have opined that "trivial or de [minimis] exposure[s]" to asbestos are not sufficient, and that "the

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mesothelioma must have been exposed to asbestos in talc, as opposed to the myriad other sources that account for exposure to asbestos common to almost the entire country's population.

335 Blount, *Amphibole Content of Cosmetic and Pharmaceutical Talcs*, ENV'T HEALTH PERSPECTIVES, 94:225-230 (1991).

336 For example, one expert for a number of the plaintiffs has offered the opinion, based on Dr. Longo's testing of only a small sampling of historical samples, that, if a plaintiff had purchased ten bottles of Johnson's Baby Powder, the chance that one or more would be contaminated with asbestos is "99.9%." 3/12/2019 Dr. Murray Finkelstein trial testimony in *Olson et al. v. Brenntag North America, Inc., et al.*, (Supr. Ct. N.Y., N.Y. Cnty., No. 190328/2017) at 3011:4-22.

337 *See* section II.F, *supra*.

exposure must be orders of magnitude [above] background" to be a "significant contributing factor in the development of mesothelioma."[338] But, citing testing such as that conducted by Dr. Longo, as well as the duration of a plaintiff's talc use and, through attempts to rewrite history with respect to the company's historic testing, they claim that individual plaintiffs have been exposed to sufficient quantities of asbestos to trigger the development of mesothelioma.[339]

Plaintiffs' experts attempt to justify that conclusion in various ways, including by reference to accepted ambient levels of asbestos, or occupational health standards (such as those promulgated by OSHA).[340] They also rely on documents estimating the level of asbestos a talc user is exposed to under certain conditions. Three oft-cited documents include: a study by Dr. Longo's lab, which purported to simulate the levels of asbestos exposure resulting from the below-the-waist use of Johnson's Baby Powder (known as the "Below the Waist" study)[341]; a document in which an Old JJCI toxicologist attempted to estimate the amounts of "airborne talc" and "hypothetical asbestos" a consumer might be exposed to if the talc is assumed to be contaminated with 10ppm asbestos;[342] and a 2014 study (the "Gordon Study"), which found that a talc-based product **from a manufacturer other than J&J** was "consistently contaminated

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338 3/4/2019 Dr. Jacqueline Moline trial testimony in *Olson et al. v. Brenntag North America, Inc., et al.*, (Supr. Ct. N.Y., N.Y. Cnty., No. 190328/2017) at 2019:16-2093:8; 3/12/2019 Dr. Jacqueline Moline trial testimony in *Olson et al. v. Brenntag North America, Inc., et al.*, (Supr. Ct. N.Y., N.Y. Cnty., No. 190328/2017) at 2826:22-2827:7.

339 Plaintiffs' experts have acknowledged that "[m]esothelioma is a dose-response disease" and that "trivial or de [minimis] exposure[s]" are not sufficient to cause mesothelioma. 3/5/2019 Dr. Jacqueline Moline trial testimony in *Olson et al. v. Brenntag North America, Inc., et al.*, (Supr. Ct. N.Y., N.Y. Cnty., No. 190328/2017) at 2181:25-2182:2; 3/12/2019 Dr. Jacqueline Moline trial testimony in *Olson et al. v. Brenntag North America, Inc., et al.*, (Supr. Ct. N.Y., N.Y. Cnty., No. 190328/2017) at 2926:11-15.

340 *See, e.g.,* 7/1/2021 Dr. William Longo trial testimony in *Prudencio v. Johnson & Johnson, et al.*, (Super. Ct. Ca., Alameda Cnty., No. RG20061303) at 4776:16-4779:2.

341 1/2018, MAS Supplemental Expert Report "Below the Waist Application of Johnson & Johnson Baby Powder, Revision #2.

342 6/2011, T. McCarthy, Ph.D., DABT, Presentation Titled Adding TEM to the Global Talc Specification, JNJ 000133180.

with asbestos" and that, when the product is applied via a "shaker test" it releases asbestos fibers into the air that could be inhaled by the user.[343]

But neither reference to asbestos regulations or the above-described documents cures the critical flaw in plaintiffs' causation case, as none of those standards or documents are probative of the likely amount of exposure experienced by a plaintiff who used talcum powder products with unknown, and potentially zero, asbestos contamination. Dr. Longo's study was designed to simulate the mode and frequency of use of a particular plaintiff (based upon her deposition testimony), and not any other user.[344] He also selected a bottle of Johnson's Baby Powder from the 1950s that was an extreme outlier in terms of alleged asbestos content.[345] The hypothetical exposure calculations by Old JJCI's toxicologist assumed a product consistently contaminated with a specific amount of asbestos.[346] And the Gordon Study *did not even involve a J&J or Old*

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343 Ronald E. Gordon, *Asbestos in commercial cosmetic talcum powder as a cause of mesothelioma in women,* 20(4) INT. J OCCUPATIONAL ENV'T HEALTH 318, 330 (2014) ("Gordon 2014").

344 1/2018, MAS Supplemental Expert Report "Below the Waist Application of Johnson & Johnson Baby Powder, Revision #2.

345 Dr. Longo claimed to have found over 50 times more asbestos in that bottle (15,100,000 str/g) than the highest concentration container for the samples that his laboratory analyzed from J&J's historic archive (268,000 str/g). *Compare* Longo Aug. 2, 2017 Rep. *with* Expert Report of Dr. William Longo and Dr. Mark Rigler "The Analysis of Johnson & Johnson's Historical Product Containers and Imerys' Historical Railroad Car Samples from the 1960's to the Early 2000's for Amphibole Asbestos, 2nd Supplemental Report" (Feb. 1, 2019).

346 Certain talc plaintiffs misrepresent Old JJCI's hypothetical exposure calculation by pointing to Dr. John Hopkins' testimony in *Olson* agreeing to the question "if there was an amount of asbestos in talc that was ten parts per million [or 0.00001% by weight], it would create a dose of asbestos between 4.5 to 9.3 fibers per cc for the adult and 0.16 to 0.18 fibers per cc in diapering a baby." 4/18/2019 Dr. John Hopkins trial testimony in *Olson et al. v. Brenntag North America, Inc., et al.*, (Supr. Ct. N.Y., N.Y. Cnty., No. 190328/2017) at 6240:25-6241:6242:1. The underlying data from these calculations shows that these numbers represent *total* fibers hypothetically respired during use, not fibers per cc. 6/2/2011 J&J Letter re Detection of Chrysotile Fiber by TEM in Magnesita Talc, JNJTALC000324172; 6/2/2011 Excel Spreadsheet re Hypothetical Serpentine, JNJ000380389. And Dr. Hopkins subsequently corrected the *Olson* testimony, specifying that the calculation was total fibers inhaled rather than fibers per cc. *See, e.g.*, 5/17/2019 Dr. John Hopkins trial testimony in *Johnson et al. v. Johnson & Johnson et al.*, (Ct. Common Pleas, S.C., Richland Cnty., No. 2018-CP-40-001781) at 1338:3-20.

JJCI talcum powder product—Rather, it used a brand of product from a different company.[347]

Extrapolating levels of exposure from testing of products a plaintiff did not use, using studies or calculations involving talc known or assumed to contain asbestos, or on products *not sold by J&J or Old JJCI*, does not show—and, in nearly all cases, there is no direct evidence—that a specific plaintiff, through their use of J&J/Old JJCI talcum powder products, was exposed to any level of asbestos, let alone sufficient levels of asbestos to cause mesothelioma. That failure of proof cannot be, or at least should not be, excused simply by the fact that the plaintiff has a disease that is associated with asbestos. More is required for causation.

7. Inability to Prove Causation from Exposure to Non-Asbestos Cleavage Fragments.

As an alternative to the asbestos-contamination theory, many plaintiffs have begun to turn to allegations that "cleavage fragments" (crushed-up pieces of non-asbestiform rock)—and even talc itself—can cause mesothelioma.[348] Plaintiffs assert that there is no "medical difference" between asbestos fibers and cleavage fragments, claiming that the latter has similar chemistry and dimensions, can be inhaled and "reach the alveoli," and therefore can cause the same diseases as asbestos.[349]

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347 The specific product used in the Gordon Study was selected because it had the highest asbestos content out of 20 commercial talcum powder products tested in 1976 by Dr. Langer and Dr. Rohl of Mt. Sinai. Gordon 2014. Among those 20 products were J&J talcum powder products, which Dr. Langer and Dr. Rohl found not to be contaminated with asbestos. Rohl 1976. At least one court prohibited plaintiff's experts from relying on or testifying about the Gordon Study. *See* 7/23/2018 Order in *Weirick v. Brenntag N. Am., Inc*., (Cal. Super. Ct. L.A. Cty., No. BC656425) at 27-35. That same court also excluded Dr. Longo's "exposure" opinions and testing of historical samples not used by plaintiff. *Id*.

348 *See, e.g.,* 11/1/2019 Dr. David Egilman deposition testimony in *Hagan et al. v. Johnson & Johnson et al.*, (Super. Ct. Ca., Alameda Cnty., No. RG19019699) at 63:7-64:7. Some plaintiffs go so far as to allege that asbestos and "fibrous talc" are the same chemically and morphologically, and/or that "fibrous talc," like asbestos, can cause mesothelioma. *Id.* As with cleavage fragments, plaintiffs fail to cite any reliable scientific study or data supporting the charge that "fibrous talc" causes mesothelioma.

349 *See, e.g.*, 5/25/2018 Dr. James Webber deposition testimony in *Cabibi et al. v. Johnson & Johnson et al.*, (Super. Ct. Ca., L.A. Cnty., No. BC665257) at 31:11-32:1.

As further described in section II.C above, the term "asbestos" is specific, and refers to six minerals that can form as bundles of long, thin, very flexible fibers, when those minerals present in an "asbestiform" habit. Various regulatory authorities recognize the distinction between asbestiform and non-asbestiform minerals, and have concluded that there is no evidence that non-asbestiform minerals can cause mesothelioma.[350]

For example, in 1992, OSHA performed a review of the scientific evidence to determine whether to regulate non-asbestiform minerals as asbestos.[351] That review determined that "substantial evidence is lacking to conclude that nonasbestiform tremolite, anthophyllite and actinolite present the same type or magnitude of health effect as asbestos," and that "there is insufficient health effects evidence linking exposure to nonasbestiform [tremolite, anthophyllite and actinolite] to a heightened risk of cancer.[352] NIOSH has made similar pronouncements in a comprehensive 2011 review of the data.[353] NIOSH has stated that "nonasbestiform minerals are not 'asbestos'" and that the epidemiological evidence only indicates that exposure to asbestos

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350 In addition, one of the company's MDL experts on mesothelial and epithelial cell biology, toxicology, and cancer research, Dr. Brooke Mossman, has conducted *in vitro* experiments which "demonstrate that cleavage fragments do not induce oxidant production and markers of inflammation and cancer development," and has explained that animal studies have shown that asbestos fibers cause tumors while non-asbestos fragments do not. 2/25/2019 Expert Report of Dr. Brooke Taylor Mossman, MS, PHD, for General Causation *Daubert* Hearing, in *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs. & Prods. Liab. Litig.*, (D.N.J. MDL No. 16-2738 (FLW) (LHG)), Dkt. 9740-10 at 21. Ultimately, Dr. Mossman has concluded that cleavage fragments "do not cause changes important in the development of disease and do not cause mesotheliomas." 3/22/2018 Dr. Brooke Mossman trial testimony in *Lanzo et al. v. Cyprus Amax Minerals Co., et al.*, (Super. Ct. N.J., Middlesex Cnty., No. MID-7385-16-AS) at 6988:3-13. And, in 2020, the company completed a Comprehensive Review of Talc in which it reviewed "epidemiologic studies which evaluated the pulmonary effects of occupational exposure to non-asbestiform cosmetic talc," and found that, "[o]verall, data from epidemiologic studies do not support a causal association between occupational exposure to nonasbestiform or cosmetic grade talc and lung cancer." 3/17/2020 Johnson's Baby Talcum Powder: A Comprehensive Review, JNJTALC001465273-001465527.

351 Occupational Exposure to Asbestos, Tremolite, Anthophyllite and Actinolite. 57 Fed. Reg. 24311 (June 8, 1992).

352 *Id.*

353 *See* NIOSH Roadmap.

causes mesothelioma.[354] And, a 2019 study of 570 fibers found in lung tissues reiterated that "there is *no convincing evidence* for the pathogenicity of cleavage fragments."[355]

8. Expert Testimony Based on "Junk Science"

In light of the company's extensive historic testing program and the opinions of dozens of independent labs and experts, each of which have consistently failed to detect asbestos in J&J's/Old JJCI's cosmetic talc, plaintiff experts also have attempted to craft a different approach to "find" asbestos in the company's products. By confusing what is or is not asbestos, plaintiff experts now claim that they are finding "asbestos" in talcum powder even if they are not.

a. Confusing Asbestiform and Nonasbestiform Minerals

One of Dr. Longo's core tactics is to call particles "asbestos" even when they are nonasbestiform. For example, Dr. Longo will report every particle of "tremolite" as asbestos if it meets the counting criteria of a "fiber," even if that particle is not "asbestiform" and therefore not asbestos. Dr. Longo acknowledges that a "structure [that] comes from breaking apart non-asbestos" minerals does "not magically become, in fact, asbestos."[356] However, he concedes he will nevertheless "count it and report it in [his] reports as asbestos."[357] Dr. Longo has explained that his lab is "not making that decision" whether the particles that he identifies in J&J/Old JJCI talcum powder are asbestiform or not.[358] If his lab finds "a non-asbestiform amphibole cleavage

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354 *Id*.

355 Roggli & Green, *Dimensions of Elongated Mineral Particles: A Study of More Than 570 Fibers From More Than 90 Cases with Implications for Pathogenicity and Classification as Asbestiform vs. Cleavage Fragments*, ULTRASTRUCT PATHOL. 1-2 (2019) (emphasis added).

356 3/5/2019 Dr. William Longo trial testimony in *Rimondi et al. v. BASF Catalysts LLC, et al.,* (Super. Ct. N.J., Middlesex Cnty., No. MID-2912-17-AS) at 141:14-17.

357 *Id*. at 149:18-20.

358 7/24/2019 Dr. William Longo hearing testimony in *In re Johnson & Johnson Powder Prods. Mktg., Sales Pracs. & Prods. Liab. Litig.*, (D.N.J. No. 16-MD-2738(FLW)(LHG)), Dkt. 11640 at 582:9-19.

fragment, he will count it as an asbestos structure."[359] In other words, while Dr. Longo acknowledges he would not "***call*** that asbestos," he still would "write down in [his] report ***asbestos*** when [identifying] what that was."[360]

Dr. Longo is not alone in this approach. Plaintiff expert Dr. Steven Compton has affirmatively testified that he will call material asbestos, even when it's not:[361]

> Q. Sir, I'd like you to assume that this is a crystal of tremolite, the kind that is not asbestos. And that when it's crushed it forms all of these shapes. . . . I'd like you to assume that this long and skinny shape here is longer than 5 microns. Has an aspect ratio of 5 to 1. You'd call that asbestos; right?
>
> A. That would be counted as an asbestos fiber, yes.
>
> Q. *Even though it's not?*
>
> A. *That's correct.*

To justify this flawed methodology, plaintiff experts sometimes claim they are simply following the protocols established by the Asbestos Hazard Emergency Response Act (AHERA) regulations. They rely on the fact that a particle meets the definition of a "fiber," even though that does not in and of itself mean it is an "asbestos fiber."[362] They ignore that, what the regulations actually state "shall be recorded on the count sheet," is not a "fiber" but an "asbestos fiber."[363] They further ignore the context of the AHERA regulations: remediation—*i.e.*, the

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359 *Id.* at 579:20-580:11.

360 3/5/2019 Dr. William Longo trial testimony in *Rimondi et al. v. BASF Catalysts LLC, et al.,* (Super. Ct. N.J., Middlesex Cnty., No. MID-2912-17-AS) at 148:17-25; 149:18-20 (Dr. Longo admitting he "would count it and report it in [his] reports as asbestos.").

361 10/23/2017 Dr. Steven Compton trial testimony in *Herford et al. v. AT&T Corp., et al.*, (Super. Ct. Ca., L.A. Cnty., No. BC646315) at 934:19–935:4.

362 *See* 40 C.F.R. § 763 app. A § II.A.9.

363 *Id.* app. A § II.F.9.a (emphasis added).

process of removing asbestos from schools and other environments where it is known to be present.[364] In that situation, there is no dispute that the material being removed is asbestos. When the presence of asbestos is known and the only question is how much, there is no need to first confirm the presence of asbestos. The AHERA regulations do require confirmation that the particles are, in fact, asbestos, but that confirmation occurs at an earlier step in the analysis before the counting rules are implicated.[365]

b. Non-Existent Chrysotile

Chrysotile is a particular type of "serpentine" (as opposed to "amphibole") asbestos. Until recently, Dr. Longo had never identified chrysotile in J&J's/Old JJCI's cosmetic talc. Dr. Longo claimed that he simply never looked for it.[366] Dr. Longo *now* claims not only to find chrysotile, but to find it in nearly 100% of the cosmetic talc that he tests—a much higher rate of occurrence than for other types of asbestos that he has claimed to find.[367] To support his findings, Dr. Longo uses PLM, which, as discussed above, he has long disclaimed for testing talc. In reality, what Dr. Longo is doing is finding talc particles in the talc, and calling them asbestos.

PLM requires more subjectivity than other techniques because the mineral type is determined based on the color the particles appear under a microscope. For example, the International Standards Organization reference for chrysotile shows a largely purple particle,

364 *See, e.g.*, 15 U.S.C. § 2641(b).

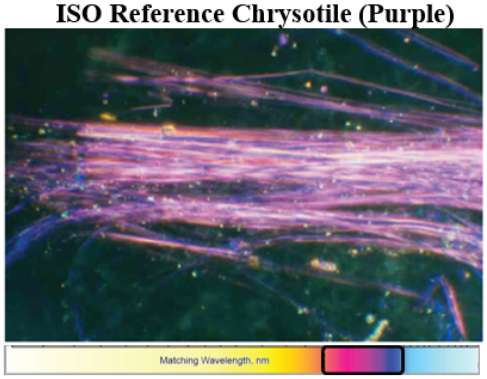
365 *See, e.g.*, 40 C.F.R. § 763.87(b) (citing Appendix E).

366 3/5/2019 Dr. William Longo trial testimony in *Rimondi et al. v. BASF Catalysts LLC, et al.,* (Super. Ct. N.J., Middlesex Cnty., No. MID-2912-17-AS) at 139:1-9; 141:2-8.

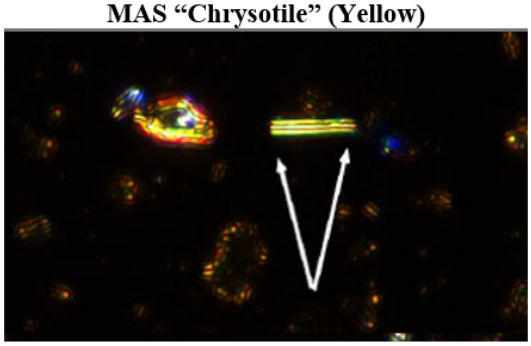
367 2/8/2021 Dr. William Longo deposition testimony in *Forrest et al. v. Johnson & Johnson et al.*, (Mo. Cir. Ct., St. Louis City, No. 1522-CC00419-02) at 138:9-139:19.

though colors can range from a deep orange to blue.[368] The "chrysotile" particles identified by Dr. Longo, however, are plainly yellow, which is the color that talc particles will appear via PLM:[369]

ISO Reference Chrysotile (Purple)



MAS "Chrysotile" (Yellow)



Even other *plaintiff experts* have agreed that Dr. Longo is identifying talc and calling it chrysotile. Plaintiff expert Mr. Lee Poye has testified, as follows:[370]

> **Q.** In your opinion, what do those photos that Dr. Longo claims is chrysotile from that -- from his PLM analysis, what are those structures?
>
> **A.** The edge of talc plates.

Dr. Longo could easily analyze these so-called chrysotile particles with TEM to conclusively prove whether or not they are chrysotile. But Dr. Longo has consistently refused to use other techniques that could confirm those opinions.[371]

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368 Particles are evaluated by PLM in both a "parallel" and "perpendicular" orientation, with each producing a different color. *See, e.g.*, ISO 22262-1. The colors referenced here are all for the parallel orientation.

369 ISO 22262-1; Expert Report of Dr. William Longo "MAS Project #M71216 Two JBP, one Gold Bond Off -The-Shelf Talcum Powder Containers: Purchased from Lucky's Talcum Powder Analysis" (Apr. 13, 2021).

370 9/25/2020 Lee Poye deposition testimony in *McNeal, Jr. et al. v. Autozone, Inc., et al.*, (Super. Ct. Ca., L.A. Cnty., No. BC698965) at 128:20-129:6.

371 *See, e.g.*, 1/27/2021 Dr. William Longo deposition testimony in *Johnson et al. v. Johnson & Johnson et al.*, (Super. Ct. Ca., L.A. Cnty., No. JCCP 4674 / 20STCV17335) at 81:19-82:18.

IV. Prejudicial Tactics Employed by the Plaintiff Bar in Cosmetic Talc Litigation

A. The Misinformation Campaign

In addition to evidentiary tactics discussed above, the plaintiff bar and their experts have sought to blanket the scientific literature, the media, and even U.S. Congressional and regulatory agency deliberations with misinformation about cosmetic talc.

1. Scientific Literature

Since their retention on behalf of plaintiffs in cosmetic talc litigation, many of the key expert witnesses for plaintiffs' counsel have flooded the scientific literature with articles repeating their opinions formed in (and motivated by) litigation. Often, this is used as a tool to combat motions *in limine* or *Daubert* attacks.

As one example, plaintiff expert Dr. Moline repeatedly attempted to testify at trials about 41 of her "patients" who she claims developed mesothelioma from using talc.[372] These "patients" were actually just plaintiffs from other cases in which plaintiff lawyers retained her as an expert witness.[373] Many courts excluded this testimony, generally prohibiting the parties from discussing the substance of cases other than the case at bar.[374]

Undeterred, Dr. Moline published a peer-reviewed article with a case series of "patients" (now narrowed to 33 "patients," all of whom, again, were plaintiffs in litigation) who she claimed developed mesothelioma from using cosmetic talc.[375] Unfortunately, courts have been

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372 *See, e.g.*, 10/26/2017 Dr. Jacqueline Moline trial testimony in *Herford et al. v. AT&T Corp., et al.*, (Super. Ct. Ca., L.A. Cnty., No. BC646315) at 1542:6-27.

373 9/5/2017 Dr. Jacqueline Moline deposition testimony in *Herford et al. v. AT&T Corp., et al.*, (Super. Ct. Ca., L.A. Cnty., No. BC646315) at 30:7-8.

374 *See, e.g.*, 4/12/2019 Order in *Hayes v. Colgate-Palmolive Co., et al.*, (Jefferson Cir. Ct., Ky., No. 16-CI-003503) at 40; 2/22/2019 Order in *Pipes v. Johnson & Johnson, et al.*, (Dist. Ct., Okla. Cnty., Okla., No. CJ-2017-3487); 2/21/2018 Order in *Lanzo v. Cyprus Amax* Mineral (Super. Ct. N.J., No. MID-7385-16-AS).

375 Moline 2020.

much more hesitant to exclude a peer-reviewed article, even where the content of the article is the same material that routinely had been excluded.[376]

The article itself presents facts skewed to favor the plaintiffs' litigation positions. One key contention in the article is that, for every subject in the study, cosmetic talc was the only potential source of asbestos exposure.[377] This is inaccurate. Though Dr. Moline has refused to disclose their identities, counsel to the company has been able to identify many of the subjects in the study as plaintiffs in cosmetic talc litigation. Through those plaintiffs' disclosures and other information obtained in litigation, counsel has identified clear evidence of their other asbestos exposures.[378] Dr. Moline has admitted that she and her co-authors often did not look at any defense expert reports for the plaintiffs that they published about.[379] And, though the article was subject to peer review, those peer reviewers did not have access to the underlying information for the individual "cases."[380] They could only accept Dr. Moline's word as to the underlying facts.

Other plaintiff experts have followed suit and published an article similar to the Moline article.[381] Rather than publish actual studies relating to talc, some experts simply send letters to

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376 *See, e.g.*, 5/18/2021 Order in *Prudencio v. Johnson & Johnson, et al.*, (Super. Ct. Ca., Alameda Cnty., No. RG20061303) (allowing plaintiff's experts to rely upon and give a "top level summary" of Dr. Moline's article).

377 Moline 2020 at 11.

378 For example, in one case that counsel was able to identify by cross-referencing information provided in the article against information in public lawsuits (Moline Case 6), the individual had a history of exposure to commercial asbestos in connection with asbestos-containing materials in his home as reported in his deposition testimony and interrogatory responses. Moreover, a review by a different plaintiffs' expert and a defense expert identified crocidolite in his tissue (a commercial type of asbestos not associated with J&J/Old JJCI talc)—contrary to Dr. Gordon's findings.

379 11/25/2019 Dr. Jacqueline Moline deposition testimony in *Wiman et al. v. Triangle Enterprises, et al.*, (Cir. Ct. Ky., No. 18-CI-00181) at 57:9-58:20; 6/11/2020 Dr. Jacqueline Moline deposition testimony in *Christina Lopez et al. v. Brenntag North America, Inc., et al.*, (Dist. Ct. Tx., Harris Cnty., No. 2017-86022-ASB) at 99:13-100:5.

380 6/11/2020 Dr. Jacqueline Moline deposition testimony in *Lopez et al. v. Brenntag North America, Inc., et al.*, (Dist. Ct. Tx., Harris Cnty., No. 2017-86022-ASB) at 82:20-84:4.

381 Emory 2020.

the editor criticizing the authors of actual studies for not sufficiently taking into account pro-plaintiff views.[382] Those letters to the editor are then cited to juries by the plaintiff expert to show the witness' supposed expertise in the talc subject matter.[383]

2. Media Campaigns

At the same time that they are litigating in court, the plaintiff bar is making their case to the potential jury pool through a variety of means, including, a steady stream of stories in widely circulated newspapers and periodicals, paid infomercials that run nightly on numerous cable channels, and one-sided press releases. These efforts typically incorporate various elements of the plaintiff bar's trial strategy.

a. National News Outlets

Since the onset of cosmetic talc litigation against J&J/Old JJCI, there have been tens of thousands of press articles concerning Johnson's Baby Powder and talc litigation. Indeed, coverage of this litigation has been relentless, by design.

Perhaps the most pernicious example of the plaintiff bar's "trial by news media" effort was an article published by Reuters in December 2018.[384] The article was one-sided and replete with inaccurate statements. Despite being provided with stacks of historic documents and hours of interviews debunking huge swaths, if not all, of its article, Reuters chose to simply ignore decades of evidence that undermined the story apparently fed to it by anonymous, plaintiff bar sources. J&J has issued subpoenas to various plaintiff firms to ascertain the information those

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382 *See, e.g.*, Egilman DE, Madigan D, Yiman M, Tran T., *Letter to the Editor: Response to Vermont talc miners cohort study update*, 62 J. OCCUPATIONAL ENV'T MED. e17-18 (2019).

383 *See, e.g.*, 2/10/2020 Dr. Murray Finkelstein trial testimony in *Moure-Cabrera v. Johnson & Johnson et al.*, (Cir. Ct. Fl., Miami-Dade Cnty., No. 19-000727) at 1067:5-25.

384 Girion, L., *Johnson & Johnson knew for decades that asbestos lurked in its Baby Powder*, REUTERS (Dec. 14, 2018).

firms may have provided to Reuters. To-date, those firms have vigorously opposed J&J's efforts to uncover this information.

A primary theme, and the most egregious misstatement, in the Reuters article was the idea that certain documents and information were being presented to the public "for the first time." The assertion was, and is, fundamentally and demonstrably untrue. Every issue raised in the Reuters article was nothing more than a rehashing of issues, concerns, documents, and debates that were played out—publicly in many instances—throughout the 1970s and 1980s, as previously described. What's more, the documents that Reuters presented as akin to secret, smoking gun type evidence had not only been used in several trials but also published on a public website—FactsAboutTalc.com—that had gone live a month prior, in November of 2018.

Beyond this false narrative of "newly exposed" information, the following are just a few examples of (i) the overwhelming documentary and scientific proof provided to Reuters well before publication that it nonetheless chose to ignore; and (ii) information that was clearly ascertainable by fact checking, but instead was woefully distorted in the article:

- Reuters ignored the findings of the Nurses' Health Study, the Women's Health Initiative Study, and the Sister Study which, as described above, showed no overall increase in the risk of ovarian cancer by women who used talc.[385] These studies were conducted by scientists at institutions including Harvard Medical School, Harvard School of Public Health, the University of Massachusetts Amherst, and the National Institute of Environmental Health Sciences. Yet Reuters did not even mention them when describing the scientific and medical evidence available concerning the connection, if any, between talc and ovarian cancer.

- Reuters reported that there were "asbestos fibers in samples taken from [J&J's] Vermont operation" in the 1980s, but it actually cited five test results from *industrial talc* samples from a *California* mine (Red Hill) that was never used for cosmetic purposes.

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385 *See* section II.D, *supra*.

- Reuters misleadingly reported that X-ray scanning was the primary method that J&J/Old JJCI used to test its talc, and that J&J/Old JJCI only periodically tested its talc with TEM when, in fact, since the 1970s, J&J/Old JJCI have implemented a rigorous routine testing program requiring hourly sampling of its cosmetic talc production and testing composites of those samples using XRD, PLM, and TEM.[386]

- Reuters falsely reported that many internal, company documents "were shielded from public view by court orders that allowed J&J to turn over thousands of documents it designated as confidential," and claimed that the contents of these documents were reported in the article for the very first time. In fact, and as already explained, every document cited in the article had not only been listed on one or more public exhibit lists for a trial, but also posted on J&J's website www.FactsAboutTalc.com.

b. Paid Infomercials

In addition to pursuing unyielding press coverage to support their efforts, it is estimated that the plaintiff bar has spent over a hundred million dollars in advertising related to cosmetic talc litigation. This spend is on top of an estimated over $1.5 million per week spent on mesothelioma advertisements by just a handful of the asbestos law firms whose advertising spend is publicly available.[387]

386 *See* section II.F, *supra*.

387 *See* publicly available LMI Market Analysis for 2018 at 15, circulated by LMI Advertising at a 2018 industry conference.

Perhaps the most egregious examples of such advertisements are those produced by CAMG, an advertising agency that works exclusively with law firms. CAMG has produced at least 39 different advertisements concerning talcum powder, including a 30-minute infomercial that has played in markets across the U.S. on various cable channels.[388] The infomercial consists of two alternating segments. The first segment is styled like a talk show. A "Dr. Wendy Walsh" sits in an armchair with a second guest, discussing studies that allegedly link talcum powder use to ovarian cancer and mesothelioma. The second segment features a female actress, speaking directly to the camera, and referencing none other than the 2018 Reuters' article while describing several out of context documents used in that article. "Doctor" Walsh never mentions that she is not a medical doctor. Nor does the female actress (also not a qualified expert as far as the Debtor is aware) address the various information provided by J&J to Reuters that was ignored in the production of the 2018 article.

388 *See* https://vimeo.com/groups/624313 to access each of the versions of the talc advertisements prepared by CAMG. For an example of the infomercial specifically, *see* https://vimeo.com/groups/624313/videos/339004183.

Finally, the plaintiff bar's advertising has been strategically targeted at forums where plaintiffs are bringing suit. By way of example, as trials have approached in St. Louis, spending in that market has spiked, saturating the airwaves in the days leading up to *voir dire*.

3. Government Lobbying

Potential juries are not the only targets of the plaintiff bar's media blitz. Plaintiff lawyers also have sought the attention of Congress. On December 10, 2019, three plaintiff expert witnesses gave testimony to the House of Representative's Subcommittee on Economic and Consumer Policy of the Committee on Oversight and Reform at a hearing on "Examining Carcinogens in Talc and the Best Methods for Asbestos Detection."[389] These plaintiff experts included Dr. Longo and Dr. Moline, as well as Dr. Rod Metcalf.

At the hearing, Dr. Longo testified to Congress that testing without a "heavy liquid separation" preparation method would not be sensitive enough to routinely detect asbestos in talc.[390] His testimony defies credulity for a number of reasons. First, this technique has been known to the scientific community for decades. And, as far back as the 1970s, independent experts, including scientists at the FDA, rejected the technique for its unreliability and failure to detect the most prevalent type of asbestos—chrysotile.[391] Second, no regulatory agency

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389 *Examining Carcinogens in Talc and the Best Methods for Asbestos Detection: Hearing Before the Subcommittee on Economic and Consumer Policy of the Committee on Oversight and Reform*, 116th Cong. 116-76 (2019) (statements of Dr. William Longo, Scientist, Materials Analytical Services, LLC and Dr. Jacqueline Moline, Physician, Feinstein Institutes for Medical Research at Northwell Health), *available at* https://www.congress.gov/event/116th-congress/house-event/LC64684/text?s=1&r=4.

390 *See id*.

391 9/6/1973 FDA Technical Plan Quarterly Project Progress Reports, Project Title: Asbestos and Other Contaminants in Talc [Recently identified on publicly filed exhibit list in *Prudencio* at DX-18188]; 9/13/1973 Memorandum Regarding Summary Papers Prepared by Professor Pooley for September 12, 1973 Meeting and 11/19/1973 Memorandum Regarding Pooley's Response to the Proposed FDA Optical Method for Detection of Asbestos in Talc - Project No. 0503.00, JNJ000264500-513.

anywhere in the world has adopted Dr. Longo's heavy liquid separation technique.[392] Third, amphibole asbestos can and has been detected in talc without using heavy liquid separation—other scientists detect the same amphibole particles as Dr. Longo, but determine the particles are not asbestos.[393] Thus, sensitivity is not the issue; rather, the issue is accurately characterizing what is being detected.[394]

Dr. Moline then testified that there are no health differences between asbestiform and non-asbestiform minerals.[395] Notably, before she was paid to testify against J&J/Old JJCI, Dr. Moline testified that the epidemiologic studies of talc miners and millers who were exposed to large quantities of talc (which would include exposure to any trace contaminants therein such as non-asbestiform minerals) did not find that the miners and millers were at increased risk of contracting asbestos-related diseases, including mesothelioma.[396] Dr. Moline has also testified in J&J/Old JJCI cases that epidemiologic studies are the gold standard for establishing causation.[397] Only after testifying against J&J/Old JJCI did Dr. Moline change her opinion and state that those studies of talc miners and millers were inadequate.

Setting aside the contrary epidemiologic evidence, Dr. Moline's testimony was simply incorrect. As discussed above, a number of well-respected regulatory authorities focused on scientific evidence-based analysis have concluded that trace amounts of non-asbestiform

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392 10/19/2018 Dr. William Longo trial testimony in *Allen v. Brenntag North America, Inc., et al.*, (Super. Ct. Ca., Humboldt Cnty., No. DR 180132) at 3583:12-17.

393 *See* sections II.C & D discussing historic findings of "tremolite" in Italian and Vermont talc.

394 *See, e.g.*, 8/2/2021 Dr. Matthew Sanchez trial testimony in *Prudencio v. Johnson & Johnson, et al.*, (Super. Ct. Ca., Alameda Cnty., No. RG20061303) at 7948:19-7949:4.

395 *See* footnote 389, *supra*.

396 2/15/2012 Dr. Jacqueline Moline trial testimony in *Thoma et al. v. A.R. Winarick, Inc., et al.*, (Super. Ct. N.J., Middlesex Cnty., No. MID-L-7891-10-AS) at 1112:10-1113:1

397 5/7/2018 Dr. Jacqueline Moline trial testimony in *Anderson et al. v. Borg-Warner Corp., et al.*, (Super. Ct. Ca., L.A. Cnty., No. BC666513) at 1283:21-25.

minerals do not present a health risk.[398] Moreover, Dr. Moline's litigation opinions, repeated as if fact to Congress, were recently thrown out by the New Jersey Superior Court, Appellate Division in *Lanzo*, precisely because they lack reliability. As further described below, the appellate court held that the admission of expert testimony that cleavage fragments that do not grow in an asbestiform habit have the same capacity to cause mesothelioma as asbestos fibers was reversible error and, as a result, granted a new trial.[399] The court further found that (i) the experts who offered this testimony, including Dr. Moline, were unable to identify a study to support their conclusions, (ii) the theory has not been subjected to peer review, and (iii) it is not widely accepted in the scientific community.[400]

Congress, however, was provided none of this context and continued its investigations and inquiries into the company based, in part, on the misinformation presented by these experts.

B. Actions in the Tort System

The plaintiff bar's trial tactics in the talc litigation have been similarly abusive.

1. Consolidation of Plaintiffs

Some of J&J's/Old JJCI's most shockingly high plaintiff verdicts have come when courts have permitted plaintiffs' counsel to consolidate multiple plaintiffs in a single case. Plaintiffs pursue consolidation because it allows them to bolster their case by stacking their allegations on top of other plaintiffs' allegations. If the jury hears the claims of multiple plaintiffs who used Johnson's Baby Powder and subsequently developed mesothelioma, the jury may well assume that the plaintiffs' allegations have merit.

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398 *See* section III.C.7, *supra*.

399 *Lanzo v. Cyprus Amax Minerals Co.,* 467 N.J. Super. at 517-18.

400 *Id.* at 510-18.

The more dissimilar the cases, the more this effect compounds. The unique facts of each case are often critical to the company's various defenses. But, the jury may not be able to keep track of the key differences between the cases or may simply overlook them. When faced with multiple plaintiffs, juries are unable to "compartmentaliz[e] certain evidence that applies to one case but not the other."[401] The company's talc trials with a single plaintiff involve complicated scientific arguments that are difficult enough for any layperson to understand. Consolidation multiplies the scientific and factual concepts that the jury must grapple with, making the trial and the jury's determination exponentially more difficult and complex.

As a result, by trying claims together, "one plaintiff, despite a weaker case of causation, could benefit merely through association with the stronger plaintiff's case."[402] This phenomenon has a name: the "perfect plaintiff"—*i.e.*, a composite plaintiff "pieced together for litigation" based on "the most dramatic" features of each individual case.[403] Numerous jurisdictions have all but ended the practice of consolidated asbestos trials because such trials are unfair and fuel the filing of more claims.[404] Not all jurisdictions have taken such steps, and it is no coincidence that the company continues to be sued in those holdout jurisdictions.

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401 *Minter v. Wells Fargo Bank, N.A.*, 2012 WL 1963347, at *1 (D. Md. May 30, 2012).

402 *Rubio v. Monsanto Co.*, 181 F. Supp. 3d 746, 758 (C.D. Cal. 2016).

403 *Broussard v. Meineke Discount Muffler Shops, Inc.*, 155 F.3d 331, 344 (4th Cir. 1998).

404 **Delaware:** Standing Order No. 1 at ¶ 4 *In re Asbestos Litig.*, No. 77C-ASB-2 (Del. Super Ct. New Castle County Oct 10, 2013) *available at* https://bit.ly/2BHC6q4 ("Each asbestos action filed hereafter shall consist of one plaintiff."); **Georgia:** Ga. Code Ann. § 51-14-11 (prohibiting consolidation of asbestos claims for trial absent consent unless the plaintiffs are members of the same household); **Iowa:** Iowa Code Ann. § 686B.7(4)(a) (same); **Kansas:** Kan. Stat. Ann. § 60-4902(j) (same); **Michigan:** *Prohibition on "Bundling" Cases,* Admin. Order No. 2006-6 (Mich. Aug. 9, 2006), *available on Westlaw as*: MI R ADMIN Order 2006-6 ("[N]o asbestos-related disease personal injury action shall be joined with any other such case for settlement or for any other purpose, with the exception of discovery."); **Mississippi:** (the Mississippi Supreme Court has issued a series of decisions severing joint asbestos claims) (*see Harold's Auto Parts, Inc. v. Mangialardi*, 889 So. 2d 493, 495 (Miss. 2004); *3M Co. v. Johnson*, 895 So. 2d 151, 158-60 (Miss. 2005); *Illinois Cent. R.R. Co. v. Gregory*, 912 So. 2d 829, 831 (Miss. 2005); *Amchem Prod., Inc. v. Rogers*, 912 So. 2d 853, 858 (Miss. 2005); *Albert v. Allied Glove Corp*., 944 So. 2d 1, 3 (Miss. 2006); **Ohio:** Oh. Civ. R. 42(A)(2) (prohibiting consolidation of asbestos claims for trial absent consent

As one example, even after acknowledging that consolidation could cause "great prejudice"[405] to J&J/Old JJCI, a New Jersey trial court *sua sponte*[406] ordered the consolidation of four plaintiffs' claims into one trial.[407] The court then implemented unwarranted and uncharacteristic procedures for punitive damages. At the end of the liability phase of the trial, the court dismissed the jury who had heard the case and empaneled a new jury for the punitive damages phase.[408] The trial court then prohibited J&J/Old JJCI from presenting to the second jury any arguments concerning weaknesses in the plaintiffs' science case on the ground that those arguments were not relevant to punitive damages.[409] A jury who was required to accept without question that asbestos was present in J&J's/Old JJCI's talc products and who did not themselves previously award any damages for the alleged conduct led to a predictable result: an award of

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unless the plaintiffs are members of the same household); **Tennessee:** Tenn. Code Ann. § 29-34-306(b) (same); **Texas:** Tex. Civ. Prac. & Rem. Code Ann. § 90.009 (for asbestos claims: "Unless all parties agree otherwise, claims relating to more than one exposed person may not be joined for a single trial."); **West Virginia:** W. Va. Code Ann. § 55-7G-8(d)(1) (prohibiting consolidation of asbestos claims for trial absent consent unless the plaintiffs are members of the same household).

405 9/28/2018 hearing transcript in *Barden, et al. v. Brenntag North America, Inc., et al.*, (Super. Ct. N.J., Middlesex Cnty., Case Nos. MID-1809-17-AS; MID-L-0932-17-AS; MID-L-7049-16-AS; MID-L-6040-17-AS) at 53:5-8.

406 Interestingly, before ordering consolidation *sua sponte*, the court rejected multiple plaintiffs' requests to consolidate. *See, e.g.,* 12/21/2018 Order in *Ruman et al. v. BASF Catalysts LLC et al.*, (Super. Ct. N.J., Middlesex Cnty., No. MID-L-02919-17-AS); 1/30/2019 Order in *Arvelo v. Asbestos Corp. LTD., et al.*, (Super. Ct. N.J., Middlesex Cnty., No. MID-L-588-17-AS).

407 2/1/2019 Order in *Barden, et al. v. Brenntag North America, Inc., et al.*, (Super. Ct. N.J., Middlesex Cnty., Case Nos. MID-1809-17-AS; MID-L-0932-17-AS; MID-L-7049-16-AS; MID-L-6040-17-AS).

408 9/11/2019 trial transcript in *Barden, et al. v. Brenntag North America, Inc., et al.*, (Super. Ct. N.J., Middlesex Cnty., Case Nos. MID-1809-17AS; MID-L-0932-17AS; MID-L-7049-16-AS; MID-L-6040-17-AS) at 77-78.

409 1/13/2020 trial transcript in *Barden, et al. v. Brenntag North America, Inc., et al.*, (Super. Ct. N.J., Middlesex Cnty., Case Nos. MID-1809-17-AS; MID-L-0932-17-AS; MID-L-7049-16-AS; MID-L-6040-17-AS) at 80:13-18.

massive punitive damages. The jury's award was $750 million (over 4 times higher than the state-law statutory maximum).[410]

2. Forum Shopping

Nowhere has consolidation had a more detrimental result than in the *Ingham* ovarian cancer case, which featured a significant case consolidation coupled with clear forum shopping. In that case, the St. Louis, Missouri, trial court permitted the consolidation of *22* plaintiffs for a single trial.[411] Plaintiffs submitted claims implicating the laws of 12 different states.[412] The court's jury instructions covered 142 pages and took over five hours to read.[413] After over 30 witnesses and a six-week trial, the jury deliberated for only eight hours. The jury found defendants J&J and Old JJCI liable for every claim.[414] The jury further awarded every plaintiff family exactly $25 million in compensatory damages despite prognoses and health outcomes ranging from individuals who had passed away from ovarian cancer to those who were in remission, including one woman who had been in remission for so many decades that she could be considered cured.[415] The total compensatory award was $550 million, with a punitive award for *$4.14 billion*.[416]

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410 2/6/2020 Jury Verdict Sheet in *Barden, et al. v. Brenntag North America, Inc., et al.*, (Super. Ct. N.J., Middlesex Cnty., Case Nos. MID-1809-17-AS; MID-L-0932-17-AS; MID-L-7049-16-AS; MID-L-6040-17-AS).

411 *Ingham*, 608 S.W.3d at 677.

412 *Id.* at 680.

413 7/10/2018 trial transcript in *Ingham et al. v. Johnson & Johnson et al*., (Mo. Cir. Ct., St. Louis City, No. 1522-CC10417-01) at 5891:23-25.

414 *Ingham*, 608 S.W.3d at 680.

415 *Id.* at 680-82.

416 *Id.* at 680. This punitive damages award was later reduced on appeal to approximately $1.6 billion. *Id.* at 724-25.

a. Plaintiffs Manufacture Personal Jurisdiction in Missouri

This extraordinary damages award resulted, in part, from the case being brought in plaintiffs' preferred forum of St. Louis, Missouri. Of the 22 plaintiffs, however, 17 had no meaningful connection to Missouri—they did not reside in Missouri, did not purchase any of J&J's/Old JJCI's talc products in Missouri, did not rely on Missouri advertising, and were not injured in Missouri.[417] Accordingly, the company moved to dismiss the non-Missouri plaintiffs for lack of personal jurisdiction.[418] The trial court denied the motion to dismiss.[419]

After the trial court's ruling, the Supreme Court issued its opinion in *Bristol-Myers Squibb Co. v. Superior Court*, 137 S. Ct. 1773, 1781 (2017), ruling that personal jurisdiction over one plaintiff could not establish personal jurisdiction over another plaintiff in the same case with similar claims. This decision eliminated the basis for personal jurisdiction over the non-Missouri defendants in *Ingham*. Shortly thereafter, in a similar talc case pending against the company, based on the Supreme Court's ruling in *Bristol-Myers Squibb,* a Missouri appellate court concluded that no personal jurisdiction existed over claims brought by a non-Missouri plaintiff.[420]

After those decisions, the non-Missouri plaintiffs in *Ingham* had to find a new jurisdictional hook. What occurred was a mass epiphany among the non-Missouri plaintiffs (and none of the Missouri plaintiffs). Each of the plaintiffs had previously filled out "plaintiff fact sheets" stating under oath the products that they used. None of the plaintiff fact sheets mentioned a product called Shower to Shower Shimmer Effects ("Shimmer"), a glittery body

417 *Id.* at 678.

418 *Id.*

419 *Id.* at 679.

420 *Estate of Fox v. Johnson & Johnson*, 539 S.W.3d 48 (Mo. App. 2017).

powder Old JJCI sold in nominal amounts between 2005 and 2010. Old JJCI contracted with Pharma Tech, a Missouri manufacturing-for-hire company, to mix and package Shimmer and to affix a label Old JJCI designed in New Jersey. After the Supreme Court's decision in *Bristol-Myers Squibb*, 15 of the 17 non-Missouri plaintiffs suddenly remembered using Shimmer. This change-of-testimony had only one purpose—to revive the plaintiffs' now defunct personal jurisdiction arguments.

Several of the 15 non-Missouri plaintiffs who now recalled using Shimmer could not say when they used it. One plaintiff testified that the idea she might have used Shimmer came to her in a dream the night before her deposition, when her lawyer mentioned the product to her. "[K]nowing my whimsical ways," she testified, "I would have bought it."[421] This plaintiff also said that she thought she would have made those purchases up to 40 years earlier, decades before Shimmer was ever sold.[422] Another plaintiff first made her claim about Shimmer use after meeting with her attorney two days before her deposition, explaining that she remembered that she "liked shiny things" around 2005.[423] Based on these new claims, the trial court found personal jurisdiction over the non-Missouri plaintiffs—even the two non-Missouri plaintiffs who never even alleged using Shimmer.[424]

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421 6/14/2018 Donna Packard trial testimony in *Ingham et al. v. Johnson & Johnson et al.*, (Mo. Cir. Ct., St. Louis City, No. 1522-CC10417-01) at 2284-86.

422 *Id.* at 2287-88

423 2/2/2018 Monica Sweat deposition testimony in *Ingham et al. v. Johnson & Johnson et al.*, (Mo. Cir. Ct., St. Louis City, No. 1522-CC10417-01) at 77:17-78:16; 81:7-12.

424 *Ingham*, 608 S.W.3d at 693-94. The appellate court ultimately reversed the decision with respect to those two plaintiffs. *Id.*

b. Plaintiffs Maximize the Benefit of Their Preferred St. Louis Venue

In addition to manipulating personal jurisdiction to bring the case in the state of Missouri, plaintiffs manipulated the system to bring the case specifically in St. Louis.[425] The reason St. Louis is plaintiffs' preferred venue—and why they work so hard to bring so many cases there—was clear from the trial. For example, at a pre-trial hearing, plaintiffs' counsel agreed that he would not mention at trial a highly prejudicial (and irrelevant) study relating to stillborn babies; the court responded that if plaintiffs' counsel mentioned the issue, it would require a new trial.[426] Yet, during opening statements, and over J&J's/Old JJCI's objection, plaintiff's counsel told the jury: "There's a study that was done where *they took stillborn children. These are children, stillborn babies. Never had a breath. They were born dead. Okay. You got me? Born dead.* And they did a biopsy on the children and discovered . . . that these babies from the womb had asbestos in them."[427] The plain design of these repeated statements was to suggest to the jury that asbestos in the company's products had killed the babies and to link cosmetic talc products to stillborn babies—an outrageous and totally unsupported inference. The company's objection was overruled, and there were no ramifications for this misconduct.

In addition, throughout trial, counsel used prejudicial demonstratives, most notably one that depicted J&J pushing a woman off a cliff into ovarian cancer:

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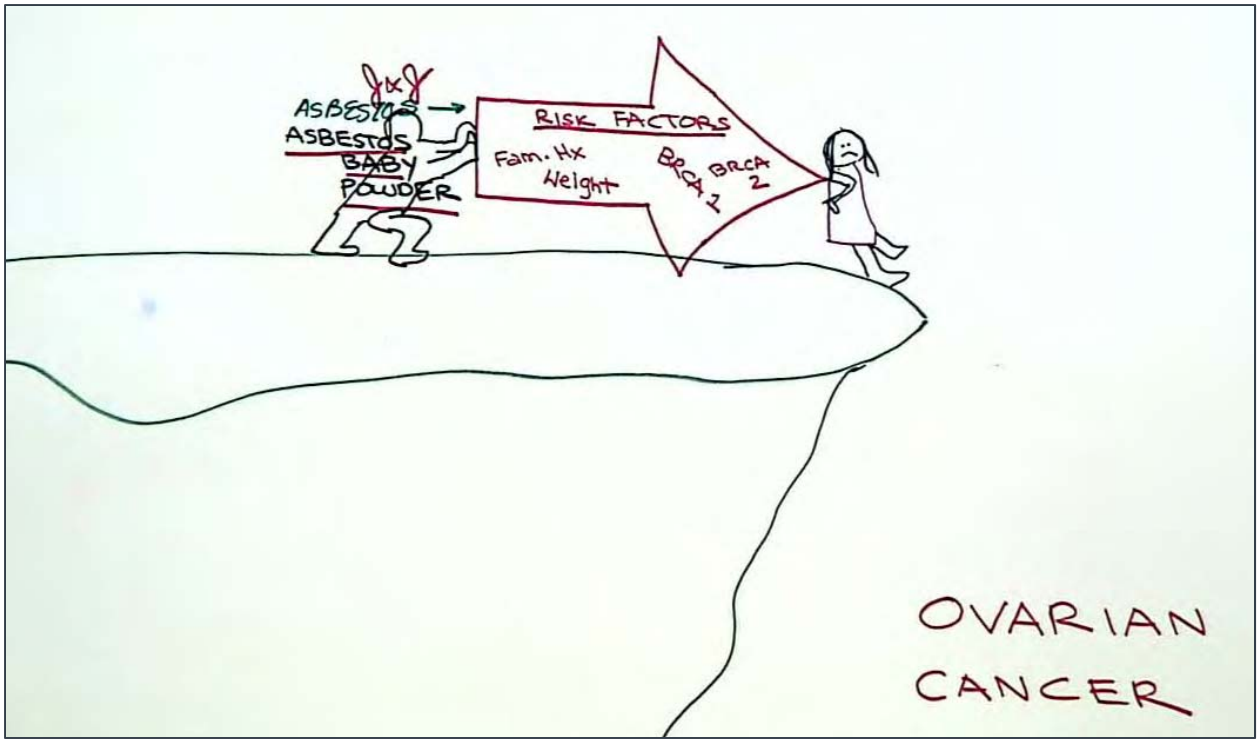
425 Only one plaintiff had any connection to St. Louis. 5/15/2018 Order in *Ingham et al. v. Johnson & Johnson et al.*, (Mo. Cir. Ct., St. Louis City, No. 1522-CC10417-01).

426 5/30/2018 hearing transcript in *Ingham et al. v. Johnson & Johnson et al.*, (Mo. Cir. Ct., St. Louis City, No. 1522-CC10417-01) at 135:1-7 ("I think we all go home and have another six weeks down the road. We'd be rescheduling.").

427 6/6/2018 trial transcript in *Ingham et al. v. Johnson & Johnson et al.*, (Mo. Cir. Ct., St. Louis City, No. 1522-CC10417-01) at 803:21-804:8.



And, among many other examples of objectionable conduct, plaintiffs' counsel told the jury during closing arguments (over the company's objection) that but-for causation is "made up."[428] Counsel made this statement to the jury notwithstanding the fact that the law in Missouri is that the "'but for' test for causation is applicable in all cases" with one exception not applicable in *Ingham*.[429]

Appellate review of the *Ingham* verdict—the largest verdict in Missouri history—was shockingly limited. The Missouri Supreme Court did not even agree to hear the case.[430] Then Justices Alito and Kavanaugh recused themselves from J&J's and Old JJCI's certiorari petition to

428 7/11/2018 trial transcript in *Ingham et al. v. Johnson & Johnson et al.*, (Mo. Cir. Ct., St. Louis City, No. 1522-CC10417-01) at 6081.

429 *Callahan v. Cardinal Glennon Hosp.*, 863 S.W.2d 852, 862 (Mo. banc 1993).

430 *Ingham v. Johnson & Johnson*, SC 98674 (Nov. 3, 2020 Mo. S. Ct.).

the U.S. Supreme Court, which was denied.[431] Getting 4 votes out of 9 justices for a grant of certiorari is hard enough; 4 of 7 is considerably more difficult.

c. Other Examples of Forum Shopping

St. Louis is not the only destination for forum shopping in cosmetic talc litigation. On the mesothelioma docket, two favored jurisdictions are California and New York.

In California, living plaintiffs are granted expedited status, which means that claimants can "skip the line" with a new filing. Once a case is granted so-called "preference" status, discovery moves at a rapid pace, and cases can move from filing to trial in under a year. Moreover, as described more fully below, certain of the state courts in California (such as Alameda Co.), are known for permitting lengthy trials, which can be prejudicial for defendants.

Similarly, in New York, the New York City Asbestos Litigation ("NYCAL") uses an expedited system for cases with living plaintiffs. Further, NYCAL essentially consolidates groups of dissimilar cases for discovery and pre-trial work up and permits consolidation for trial—collectively, these case management procedures can be extremely prejudicial for defendants.

3. Extended Trials

In addition to forum shopping and consolidation, J&J and Old JJCI have been subject to a number of other litigation tactics that contribute to their ballooning defense spend and trial risk. One such tactic is the effort by plaintiffs to extend trials out as long as possible. Cosmetic talc cases can be tried in 2-3 weeks. Such trials have even been completed over 7 trial days.[432] Yet, plaintiffs' counsel have sought and courts have permitted extension of cosmetic talc trials for

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431 *Johnson & Johnson v. Ingham*, No. 20-1223, *cert. denied* (S. Ct. June 1, 2021).

432 *Johnson v. Johnson & Johnson, et al.*, (S.C. Ct. Common Pleas 2019, No. 18-CP-40-1781).

months.[433] The plaintiff's strategy, in those circumstances, is to put on numerous and redundant expert witnesses over an extended time period. This is designed to make it difficult for a jury to conclude that all of the time spent and all of the testimony that they heard concerned a perfectly safe product.

Indeed, trial length appears to be one of the biggest factors in determining the direction and size of a verdict. For example, the average number of trial days[434] for the trials resulting in J&J/Old JJCI's 10 mesothelioma defense verdicts was 16.3 days.[435] For the mesothelioma trials resulting in 10 plaintiff verdicts, however, the average number of trial days was 30.3 days.[436] And, the longest mesothelioma trials have led to the largest verdicts, each in excess of $100 million and driven by extraordinary punitive damages awards, whereas shorter trials have had significantly smaller verdicts.[437] These longer trials also cost Old JJCI significantly more to defend and are contributing to the ballooning defense costs discussed below.

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433 A recent trial lasted approximately two-and-a-half months. *Prudencio v. Johnson & Johnson*, (CA Sup. Ct. 2021, No. RG20061303).

434 For purposes of this analysis, "trial days" were calculated based on trial days from opening to closing statements, not counting *voir dire*.

435 *See Johnson v. Johnson & Johnson, et. al.,* (S.C. Ct. Common Pleas 2019, No. 18-CP-40-1781) (7 trial days), *Crudge* (12 trial days), *Henry et al. v. Brenntag North America, Inc., et al.*, (Super. Ct. N.J., Middlesex Cnty., No. MID-1784-17-AS) (13 trial days), *Hayes* (13 trial days), *Rimondi* (16 trial days), *Herford* (17 trial days), *Blinkinsop et al. v. Albertsons Companies, Inc., et al.*, (Super. Ct. Ca., L.A. Cnty., No. BC677764) (18 trial days), *Weirick* (20 trial days), *Allen* (23 trial days), and *Pui Fong et al. v. Johnson & Johnson et al.*, (Super. Ct. Ca., L.A. Cnty., No. BC675449) (24 trial days).

436 *See Anderson* (12 trial days), *Moure-Cabrera* (12 trial days), *Cabibi* (16 trial days), *Schmitz v. Johnson & Johnson et al.*, (Super. Ct. Ca., Alameda Cnty., No. RG18923615), (26 trial days), *Johnson v. J&J, et al.*, (Super. Ct. CA., Los Angeles Cnty., No. 4674/20STV17335) (27 trial days), *Leavitt* (34 trial days), *Lanzo* (39 trial days), *Barden* (42 trial days), *Prudencio* (45 trial days), and *Olson* (50 trial days).

437 *Compare Lanzo* (39 trial days, $117 million verdict), *Olson* (50 trial days, $325 million verdict), and *Barden* (42 trial days, $787 million verdict); *with Moure-Cabrera* (12 trial days, $9 million verdict) and *Anderson* (12 trial days, $25.7 million verdict).

4. Assertion of Unsubstantiated Claims

In their efforts to grow the cosmetic talc litigation industry, plaintiffs' counsel has amassed vast listings of individuals diagnosed with ovarian cancer or mesothelioma. These lists have been used to assert claims against Old JJCI and J&J in an effort to coerce settlement. As a plaintiff's counsel recently was forced to concede under oath, certain plaintiffs' counsel took the list and asserted claims against Old JJCI and J&J without even assessing whether the claimant had been exposed to the talc used in Johnson's Baby Powder, and in some cases, pursued such claims even though the claimant had previously alleged and recovered on a theory that the disease was exclusively attributable to other products.[438] When presented with evidence of mass assertion of claims without any due diligence by plaintiffs' counsel in the Imerys Bankruptcy, the court there excluded 15,719 votes proffered by that firm in favor of the proposed plan, since, among other things, there was no diligence by the firm that any of such voters had claims against the debtor.[439]

Indeed, in the few short years since cosmetic talc litigation started to explode, the company has discovered numerous instances of plaintiff misconduct in the form of unsubstantiated claims. The following are just some examples:

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438 *See* 9/20/2021 telephonic hearing transcript in *In re Imerys Talc America, Inc.*, (D. Del. Bankruptcy Ct., No. 19-10289-LSS) at 52:1-56:15, 60:16-22, 63:11-64:2, 66:10-67:10, 67:22-68:19.

439 *See* Opinion at 27, *In re Imerys Talc America, Inc.*, No. 19-10289 (LSS) (Bankr. D. Del. Oct. 13, 2021), Dkt. 4239. In denying counsel's motion under Bankruptcy Rule 3018, the court concluded that "the evidence raise[d] significant questions as to whether any of Bevan & Associates' clients have a claim against any Debtor." *Id.* at 25. In particular, the court found that, "[w]hat is crystal clear is that: (i) Bevan & Associates has a database of clients built up over the past thirty years, (ii) prior to voting, Bevan & Associates performed zero diligence to discern which of its clients, if any, had been exposed to talc, much less to Debtors' talc and (iii) Bevan & Associates submitted its Master Ballot without regard to whether any of its 15,713 [sic] clients had a Talc Personal Injury Claim as required to vote on the Plan. In other words, Bevan & Associates simply printed out a list of its clients in excel spreadsheet format and slapped it behind a Master Ballot." *Id.*

In one case, plaintiff claimed he used Johnson's Baby Powder for years on himself and others. The evidence demonstrated, however, that the timeframe in which he claimed he used Johnson's Baby Powder coincided with his military service on a military base away from those family members on whom he allegedly used Johnson's Baby Powder. The company was forced to litigate and uncover the issue, ultimately resulting in the plaintiffs' dismissal of the case.

In another case, the plaintiff's wife testified that she purchased around 5,500 containers of Johnson's Baby Powder during the period from 1985 through 2017. If accurate, that would mean that the family used more than three full bottles of baby powder a week for decades. But, the records of purchase from various retailers did not add up. Extensive records of the family shopping at Costco, Albertsons, and RiteAid were located, but none of those records showed a single purchase of Johnson's Baby Powder (even though according to plaintiff's wife, those retailers would have accounted for nearly 2000 of the bottles).

Retailer records led to discovery of similar misrepresentations in another case. One plaintiff alleged that he used Johnson's Baby Powder at least 2 times per day for 52 years, going through several bottles a year. In discovery, the company received loyalty card records from the retailers where the plaintiff claimed to have purchased Johnson's Baby Powder. Those records identified extremely limited Johnson's Baby Powder purchases, contradicting the plaintiff's claimed extensive use. In addition, the plaintiff's lawyer blatantly hid expert reports unhelpful to his case. The plaintiff's experts conducted three tests of the plaintiff's tissue and did not find any asbestos. The plaintiff's counsel did not produce those reports, which were required to be disclosed both under California rules and under a deposition notice.[440] Moreover, an expert

[440] Any writing and report that exist at the time of the expert designation must be produced with the expert designation. CCP 2034.230(b). If none exists at the time the designation is due (report not prepared yet), any discoverable expert materials are due three business days before the expert deposition. CCP 2034.415.

responsible for one of the hidden reports even went on to testify that he wasn't aware of whether he tested any tissue from the plaintiff. Plaintiffs' counsel sat silently by at the deposition as the expert provided this inaccurate and potentially perjurious testimony. Only after that deposition was the company able to discover emails demonstrating that the expert was, in fact, aware of such testing prior to testifying at the deposition.

While applying talc should take less than a minute, the plaintiff in one case testified that she would apply talc powder products for a full *20 minutes* every day after each shower. She went on to testify that her husband also applied talc products for 10-15 minutes after each shower, and that she would be present in the bathroom for his talc use just about every time. All in all, the plaintiff claimed that she would be exposed to talc for over 30 minutes nearly every day—a simply implausible claim. In addition, in the same case, the plaintiff and her estate submitted a sworn interrogatory response stating that the plaintiff was exposed to asbestos-containing friction products through her husband who owned an automobile service center. After the plaintiff's estate focused on J&J/Old JJCI and other talc defendants as the prime targets of the case, however, they claimed that, in fact, the plaintiff was never exposed to asbestos from her husband's work.

In one extraordinary case, a hospice doctor signed a death certificate stating that the cause of the plaintiff's death was "Budd–Chiari syndrome," without any mention of mesothelioma. Plaintiff's counsel later sent a letter to that doctor falsely stating that "[p]er New Mexico Law," he "must" amend the death certificate to add mesothelioma as a contributing factor to the plaintiff's death—which the doctor did in response to the letter. New Mexico law,

of course, required no such thing.[441]

Plaintiffs' expert then relied on the changed death certificate in his testimony. In a deposition, the doctor testified that, based on the letter from counsel, he believed that he was legally obligated to add mesothelioma to the death certificate. To prevent their misconduct from becoming known, when asked for any communications with the doctor, the plaintiffs' counsel withheld the letter from their document production and falsely answered discovery responses stating that they had not sent the letter. The company only discovered the fraudulent behavior when they requested and received communications to plaintiff's counsel directly from the doctor.

C. Coopting State Attorneys General Actions

Plaintiffs' counsel has also undertaken a campaign to pressure state attorneys general to pursue alleged consumer class action claims against J&J and Old JJCI with the objective of using these actions to exert additional leverage and coerce resolution of their claims in the tort system. To date, two such actions have been filed in Mississippi and New Mexico. In particular, the Mississippi action highlights the plaintiff bar's cooption of these "state" actions: Mississippi's attorney general retained R. Allen Smith, Jr.—a plaintiff's attorney who has filed (and lost) numerous ovarian cancer claims against J&J/Old JJCI—and his law firm as "Special Assistant Attorneys General" to pursue the state's action against J&J/Old JJCI.[442] And while only two state attorneys general had initiated claims against the company as of the filing date, Mr. Smith and others have continued to lobby attorneys general in other states to pursue similar claims.

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441 *See* New Mexico Statutes Annotated, section 24-14-25 ("A certificate or report registered under the Vital Statistics Act may be amended only in accordance with that act and regulations adopted by the department pursuant to that act to protect the integrity and accuracy of vital records and health statistics.").

442 8/22/2014 Retention Agreement between Mississippi Attorney General and R. Allen Smith, Jr.

V. J&J's and Old JJCI's Litigation Results

A. J&J and Old JJCI Ultimately Prevailed in the Majority of Cases.

Notwithstanding the broad misinformation campaigns, endless resources being poured into cosmetic talc litigation, and prejudicial litigation tactics, J&J and Old JJCI generally have had success in the cosmetic talc litigation. This has included, among others things, dismissing roughly 1,300 ovarian cancer and over 250 mesothelioma cases without payment, and achieving 16 key defense verdicts to-date (including victories as to six of the eight plaintiffs whose claims were tried to a jury verdict in 2021, alone)—clear evidence that Johnson's Baby Powder and Shower to Shower are not the cause of disease. In addition, all of the ovarian cancer plaintiff verdicts to-date have been reversed on appeal with the exception of *Ingham*, which was reversed in part and the damages award reduced.

B. J&J and Old JJCI Had Significant Success in Reversing Wrongly Decided Plaintiff Verdicts.

In addition to J&J's/Old JJCI's successes dismissing cosmetic talc cases, the company has been able to reverse many wrongly decided plaintiff verdicts on appeal. In *Lanzo*, for example, the New Jersey appellate court concluded that multiple errors by the trial court in a mesothelioma case warranted a new trial. First, the appellate court concluded that the "trial court did not perform its required gatekeeping function and mistakenly exercised its discretion by permitting [plaintiffs' expert] Webber to testify that non-asbestiform cleavage fragments can cause mesothelioma."[443] The appellate court came to the same conclusion with respect to Dr. Moline's testimony in the case.[444] The appellate court explained that "[b]ased on Webber's and Moline's improper testimony, the jury could have reached the conclusion that there was more

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443 *Lanzo v. Cyprus Amax Minerals Co.*, 467 N.J. Super. at 511.

444 *Id.* at 513.

than one definition for asbestos, and that a public health definition included non-asbestiform tremolite, actinolite, and anthophyllite," particularly in light of "plaintiffs' counsel's repeated arguments echoing their unsupported views."[445]

The appellate court also concluded that a new trial for Old JJCI was warranted due to the trial court's adverse inference instruction regarding Old JJCI's supplier and co-defendant Imerys.[446] The trial court had told the jury that it could infer that Imerys' talc was contaminated with asbestos.[447] The problem, of course, is that Imerys talc and Old JJCI talc is the same talc, yet the court did not order separate trials for Imerys and Old JJCI. Accordingly, the appellate court properly ruled:

> We are convinced, however, that once the jury was permitted to draw an adverse inference that Imerys' talc was contaminated with asbestos, it would be difficult, if not impossible, for the jury not to make the same finding as to [Old] JJCI. We therefore conclude that the trial court erred by failing to sever the claims against [Old] JJCI and Imerys.[448]

In another example, *Echeverria*, a jury in California state court in Los Angeles awarded $417 million ($347 million in punitive damages) against J&J/Old JJCI to a plaintiff alleging that Johnson's Baby Powder caused her ovarian cancer. That verdict was set aside almost immediately when the trial court granted J&J's and Old JJCI's motions for judgment notwithstanding the verdict ("JNOV") and for a new trial for, among other things, lack of evidence as to both general and specific causation. In granting J&J's post-trial motion, the court stated that "[n]o published peer-reviewed articles have determined talc to cause ovarian cancer,"

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445 *Id.* at 516.

446 *Id.* at 530.

447 *Id.*

448 *Id.*

and that there had been "a lack of any proper testimony as to specific causation."[449] The appellate court partially reversed the trial court's JNOV as to Old JJCI and ordered a new trial, but the grant of JNOV in favor of J&J on all claims was affirmed.[450] Additionally, the appellate court found no basis for an award of punitive damages against Old JJCI, explaining that it was "undisputed that there has not been direct, conclusive evidence establishing genital talc use causes ovarian cancer."[451] Rather, "[t]he evidence demonstrated it is not universally accepted in the scientific or medical community that talc is even a significant risk factor for ovarian cancer."[452]

Given the state of the scientific evidence, the court concluded that "[t]here was no substantial evidence to support a finding, by clear and convincing evidence, of despicable conduct that [Old] JJCI carried out with a willful and conscious disregard of the safety of others."[453] As of the date hereof, no new trial has been set with respect to the partial reversal of the trial court's JNOV as to Old JJCI.

C. Unpredictable and Wildly Divergent Damages Awards Remain a Constant and Overwhelming Threat in the Current Tort System.

Notwithstanding J&J and Old JJCI's significant litigation successes, *every* cosmetic talc case presents risk associated with the plaintiff bar's all-out attack. Finding a jury that has not been exposed to misinformation is nearly impossible. And, while the appellate courts have provided a significant measure of relief, appellate rulings seem to do little to dissuade the barrage

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449 *See In re Johnson & Johnson Talcum Powder Cases*, No. BC628228, 2017 WL 4780572, at *3, *19 (Cal. Super. Ct. L.A. Cty. Oct. 20, 2017).

450 *Id.*

451 *Echeveria v. Johnson & Johnson*, 37 Cal. App. 5th 292, 333 (2019).

452 *Id.*

453 *Id.* at 335.

of litigation being brought by the plaintiff bar. As a result, the company has been subject to a number of plaintiff verdicts coupled with unpredictable and wildly divergent compensatory and punitive damages awards.

In mesothelioma cases, compensatory damages awards in single-plaintiff cases have ranged from just shy of $2.5 million to $40 million.[454] Punitive damages have ranged from $100,000 to $300 million.[455] And, the plaintiff bar's arguments for damages are only growing more outrageous. By way of example, in *Herford*, the first mesothelioma case against J&J/Old JJCI to go to jury verdict (ultimately ending in a defense verdict), plaintiff's counsel asked for roughly $23 million in compensatory damages.[456] But in *Johnson*, the most recent mesothelioma trial to go to verdict, plaintiff's counsel suggested to the jury that $8 billion was an appropriate sum to award in compensatory damages.[457]

In ovarian cancer cases, compensatory damages awards in single-plaintiff cases have ranged from $5 million to $70 million.[458] Punitive damages have ranged from $50 million to

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454 *See* 10/12/2021 Special Verdict Form in *Johnson v. J&J, et. al*., (Super. Ct. CA., Los Angeles Cnty., No. 4674/20STCV17335); 1/21/20 Amended Judgment on Special Verdict in *Cabibi v Johnson & Johnson et al.*, (Super. Ct. Ca., L.A. Cnty., No. BC 665257). While the $40 million compensatory award ultimately was reduced to $12 million (*see* 1/21/20 Amended Judgment on Special Verdict in *Cabibi v Johnson & Johnson et al*., (Super. Ct. Ca., L.A. Cnty., No. BC 665257)), other compensatory awards of $37 million and $29 million were not subsequently reduced. *See* 6/29/18 Order in *Lanzo v. Cyprus Amex Minerals Co., Inc. et al.,* (Super Ct., N.J., Middlesex Cnty., No. L-7385-16-AS); 5/24/2019 Order in *Leavitt v. Johnson & Johnson et al*., (Super. Ct. Ca., Alameda Cnty., No. RG17882401).

455 8/26/21 Judgment on Special Verdicts in *Prudencio v. Johnson & Johnson*, (CA Sup. Ct. 2021, No. RG20061303). The $300 million award later was reduced to $105 million. 11/30/2020 Judgment in *Olson v. Brenntag North America, Inc*., (N.Y. Sup. Ct., No. 190328/2017).

456 *See* 11/13/2017 trial transcript in *Herford et al. v. AT&T Corp. et al.,* (Super. Ct. Ca., L.A. Cnty., No. BC646315) at 3663:26-3664:13, arguing for $1 million per year for each year of lost life expectancy.

457 *See* 10/6/21 trial transcript in *Johnson v. J&J, et. al.*, (Super. Ct. CA., Los Angeles Cnty., No. 4674/20STCV17335) at 10910:3-9.

458 5/2/16 Final Verdict Form in *Ristesund v. Johnson & Johnson et al*., (Cir. Ct., St. Louis City, No. 1422-CC09012-01); 8/21/17 Judgment on Special Verdict in *Echeverria v. Johnson & Johnson et al*., (Super. Ct. Ca., L.A. Cnty., No. BC628228).

$347 million.[459] And, as discussed in further detail above, compensatory and punitive damages can skyrocket in multi-plaintiff ovarian cancer cases, reaching $550 million in compensatory damages and *$4.14 billion* in punitive damages in *Ingham*.[460]

The two plaintiffs' verdicts rendered in 2021 (out of the 6 trials to verdict)—one in which the jury awarded $25 million in compensatory damages and $100,000 in punitive damages and the other in which the jury awarded roughly $2.5 million in compensatory damages and $25 million in punitive damages[461]—demonstrate the incongruous nature of the awards in cosmetic talc cases. Further, the extraordinary range in cosmetic talc verdicts underscores the inconsistency that the company has come to expect from this litigation. And, each blockbuster verdict has resulted in substantial media attention and inevitably inspired more cases to be filed. Such verdicts also are the direct result of the various, prejudicial litigation tactics employed by the plaintiff bar that continue unchecked.

D. Supreme Court Recusals Work Significant Prejudice and Deprive J&J and Old JJCI of Review of State Court Rulings On Punitive Damages.

The continued risk of unpredictable and blockbuster verdicts—as illustrated by the wildly divergent verdicts rendered in 2021 alone—brings into even sharper focus the continued prejudice suffered by J&J and Old JJCI as a result of the Supreme Court's refusal to review the *Ingham* matter, and specifically, the approximately $1.6 billion adjusted award of punitive damages.

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459 *Id.*

460 *Ingham v. Johnson & Johnson*, 608 S.W.3d 663, 680 (Mo. App. 2020).

461 *See* 10/12/2021 Special Verdict Form in *Johnson v. J&J, et. al*., (Super. Ct. CA., Los Angeles Cnty., No. 4674/20STCV17335); 8/26/21 Judgment on Special Verdicts in *Prudencio v. Johnson & Johnson*, (CA Sup. Ct. 2021, No. RG20061303).

The Supreme Court has repeatedly held that the Due Process Clause imposes substantive limits on the imposition of punitive damages. *See TXO Prod. Corp. v. Alliance Resources Corp.*, 509 U.S. 443, 453-54 (1993) ("[T]he Due Process Clause of the Fourteenth Amendment imposes substantive limits beyond which penalties may not go."); *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 562 (1996) ("The Due Process Clause of the Fourteenth Amendment prohibits a State from imposing a 'grossly excessive' punishment on a tortfeasor."); *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 416 (2003) ("While States possess discretion over the imposition of punitive damages, it is well established that there are procedural and substantive constitutional limitations on these awards."). In light of this principle, courts across the country have long cautioned that "there is a risk that the defendant will be repeatedly punished for the same conduct, which could result in a punishment 'so irrational as to offend the due process clause of the Fourteenth Amendment.'" *In re Asbestos Prod. Liab. Litig. (No. VI)*, No. 02-MD-875, 2014 WL 3353044, at *13 (E.D. Pa. July 9, 2014) (quoting *Dunn v. HOVIC*, 1 F.3d 1371, 1405 (3d Cir. 1993)); *Roginsky v. Richardson-Merrell, Inc.*, 378 F.2d 832, 839 (2d Cir. 1967) ("We have the gravest difficulty in perceiving how claims for punitive damages in such a multiplicity of actions throughout the nation can be so administered as to avoid overkill"); *cf. State Farm*, 538 U.S. at 423 (expressing concern about "the possibility of multiple punitive damages awards for the same conduct"). Yet, given the lack of review in *Ingham*, punishment of the very same defendants for the same alleged conduct, at high ratios, over and over again—*i.e.,* punitive damage overkill—is precisely the reality that J&J and Old JJCI faced every trial.

Despite clear evidence that the *Ingham* jury believed that it was punishing J&J and Old JJCI for all of their alleged historical talcum powder-related conduct, not just harm visited on the

specific *Ingham* plaintiffs,[462] juries across the country continue to be charged that they may consider and award such damages, and some have. This is particularly concerning where, as in the recent *Prudencio* matter, the relevant trial court granted summary judgment in favor of J&J/Old JJCI as to all of that plaintiff's fraud causes of action, citing the lack of evidence to support such claims.[463] Yet, the very same trial court allowed the jury to consider and award punitive damages which, in California where the case was tried, must be based on clear and convincing evidence of malice, oppression, or fraud. *See* Ca. Civ. Code, § 3294.[464]

Finally, punitive damages are intended as a deterrent. Such a deterrent is entirely unnecessary where Johnson's Baby Powder is no longer sold in the U.S. market.

E. The Cost of Cosmetic Talc Litigation Is Now Enormous and Continues To Grow.

Further, each and every cosmetic talc claim requires an output of defense dollars. Each and every trial requires hundreds of thousands more. The cost of this sudden onslaught of litigation has been, in a word, breathtaking.

With nearly 40,000 lawsuits filed in a matter of years, in nearly every state in the country, on both state and federal dockets, with no real coordination (despite Old JJCI's requests for the same), alleging exposure to two separate products over the course of 7 decades and implicating

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462 Most notably, one of the Ingham jurors explained to reporters that the jury "arrive[d] at the $4.14 billion punitive damages amount" by "multipl[ying] the roughly $70 million Johnson & Johnson earned selling baby powder in a recent year by the 43 years it's been since the company claimed the baby powder did not contain asbestos." *See* https://www.stltoday.com/news/local/crime-and-courts/talc-cancer-verdict-of-billion-from-st-louis-jury-sends/article_c15e7f98-fce0-5a74-80ee-45371d5e98b1.html.

463 *See* 4/04/21 Order in *Prudencio v. Johnson & Johnson, et al.*, (Super. Ct. Ca., Alameda Cnty., No. RG20061303).

464 Allowing punitive damages where plaintiff's fraud claim was summarily disposed of is contrary to the law of California. *See e.g., Gawara v. U.S. Brass Corp.*, 63 Cal.App.4th 1341, 1362 (1998) (reversing trial court's award of punitive damages and holding that when a stand-alone fraud claim is dismissed, a punitive damage claim cannot proceed based on the fraud theory.)

multiple different disease types, the challenges of mounting an effective, uniform, and efficient defense have been staggering. As have the costs.

In just the last five years, the cost of outside counsel and related vendors to locate, review, and produce documents; field discovery requests; prepare and defend witnesses for deposition; locate and work with an extensive network of expert witnesses; file and respond to motions and other pleadings; and represent the Company in the 42 cases that have gone to trial, to-date, has grown to nearly $1 billion. Over the months prior to the petition date, Old JJCI was paying anywhere from $10 million to $20 million in defense costs on a *monthly basis*.[465]

Among other factors contributing to these phenomenal defense costs:

- J&J defendants have responded to hundreds of sets of discovery, including thousands of individual interrogatories (not counting subparts).
- J&J defendants have filed and responded to thousands of motions and other pleadings.
- In a matter of years, J&J defendants has been called on to produce over two and a half million pages of documents to over 40 separate law firms. The document collection was sourced from more than 130 individuals and nearly 100 other document sources.
- At the time of this filing, over 35 J&J or Old JJCI witnesses had been deposed in over 90 separate depositions, with 6 additional witnesses scheduled in the next month. Of the 90 depositions, 50 depositions have been person most knowledgeable/person most qualified ("PMK/PMQ") depositions addressing over 300 noticed topics. Collectively, these depositions span more than 150 days and roughly 33,000 pages of testimony.

Beyond the monetary cost, the time and expense to J&J and Old JJCI employees—from scientists and specialists to in house counsel and up through management—cannot be quantified, but has been overwhelming.

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465 These numbers, of course, do not account for payments on account of verdicts or the modest number of settlements undertaken to-date that, collectively, add up to approximately $3.5 billion.

And, there is little doubt that cosmetic talc litigation will only continue to grow, and the extraordinary costs continue to mount. Beyond the sudden influx of ovarian cancer claims being filed, while the company disputes that its cosmetic talc products contain any asbestos, plaintiff experts estimate that the latency period for mesothelioma can be as high as 60 years—and, similarly, have begun to allege extended latency periods for ovarian cancer allegedly caused by asbestos exposure.[466] This means that, even though Old JJCI stopped selling its talc-based Johnson's Baby Powder in North America in 2020, individuals who develop mesothelioma in 2080 and beyond may still sue J&J-related defendants, potentially drawing out the litigation to the end of this century.

VI. The Debtor Currently Faces Overwhelming On-Going Litigation Claims.

A. Ovarian Cancer Claims

As a result of the onslaught of litigation, currently the Debtor is facing approximately 38,000 ovarian cancer claims. Approximately 35,000 of those plaintiffs' suits are pending in the MDL, nearly 3,300 claims are pending in multiple state court jurisdictions across the country, with roughly 2,200 of those claims consolidated in formal state court proceedings in California and in New Jersey. More than the sheer number of pending lawsuits, the acceleration of ovarian cancer claims has been staggering. In 2014, J&J/Old JJCI were served with 46 ovarian cancer complaints. In 2017—just three years later—that number was nearly 5,000. This extraordinary acceleration in ovarian cancer claims asserted against J&J/Old JJCI has shown no signs of abating. As of the petition date, J&J/Old JJCI had been served with *over 12,300* ovarian cancer complaints in just the first ten and a half months of 2021.

466 *See, e.g.*, Expert Report of Jaqueline Moline (November 4, 2019).

YEAR	OVARIAN CANCER COMPLAINTS	NUMBER OF PLAINTIFFS
2014	46	426
2015	131	907
2016	325	2,082
2017	4,824	6,300
2018	5,745	6,328
2019	4,425	4,727
2020	9,856	9,856
2021[467]	Over 12,300	Approximately 13,000

To put the pace of this litigation in perspective, from 2017 through 2019, the company was served on average with one or more ovarian cancer complaints *every other hour of the day, every single day of the week*. From January 2020 to the present, however, the company has been served on average with one or more ovarian cancer complaints *every hour of the day, every single day of the week*.

With roughly 21,000 new ovarian cancer diagnoses each year,[468] and little preventing the plaintiff bar from alleging that the company's products were at fault, there is no end to the claims that may be asserted against the Debtor.

B. Mesothelioma Claims

In addition, as of the petition date, there were more than 430 mesothelioma cases pending against J&J/Old JJCI nationwide, nearly all of which were pending in state court.[469] The majority of these cases (well over 250) are pending in Middlesex County Superior Court in New Jersey. However, a substantial number of cases are pending in state courts in New York, Illinois, California, Missouri, and Ohio, with the remainder of the cases pending in various state court

467 Numbers listed for 2021 are as of the petition date.

468 SEER Data.

469 At no time has there been more than five mesothelioma cases pending in federal courts across the country.

jurisdictions across the country.[470] The nationwide scope of the litigation further increases the costs of defense given, among other things, variable procedural and substantive law across jurisdictions. For example, prepetition, the company was regularly forced to re-litigate various evidentiary issues that had already been litigated in another jurisdiction, often resulting in different outcomes.

Though not as extreme in number as the ovarian cancer filings, mesothelioma filings against the company have trended upward over recent years—even though traditional mesothelioma filings have decreased.[471]

YEAR	MESOTHELIOMA CASE FILINGS
2017	257
2018	371
2019	326
2020	271
2021[472]	Over 120

Given that the evidence demonstrating the absence of asbestos in J&J's/Old JJCI's cosmetic talc products has not changed—and claims that talc, itself, causes mesothelioma are unsupported by science—the increase in claims against the company while overall mesothelioma claims are dropping is directly attributable to the plaintiff bar's desire to fill the gap in their claim inventories with claims against a new and solvent defendant.

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470 At the time of filing, one or more mesothelioma cases are pending in the state courts of each of the following: Arizona, Arkansas, California, Connecticut, Delaware, Florida, Georgia, Illinois, Indiana, Kentucky, Louisiana, Massachusetts, Michigan, Minnesota, Missouri, New Jersey, New York, Ohio, Pennsylvania, Oklahoma, Rhode Island, South Carolina, Texas, and Washington.

471 *See* section III.A.1, *supra*.

472 Case filings for 2021 are as of the petition date.

VII. The Debtor's Objectives in this Chapter 11 Case

The Debtor commenced this chapter 11 case to bring about a rational resolution to the talc litigation against it in a manner beneficial to both the Debtor and any legitimate claimants. Among the Debtor's goals in this case is to establish a fully funded trust that will provide any legitimate current and future claimants with a simpler, more streamlined process to get funds in a timely manner than that currently available in the tort system. Such a trust would allow such claimants to resolve their claims through an administrative process that reduces transaction costs and spares claimants the delay, uncertainty, and stress of litigation.

The Debtor intends to pursue the following steps to achieve its goals in this case.

A. Early Case Resolution Discussions

One of the initial steps in this chapter 11 case is the appointment of an official talc claimants' committee (the "TCC") to represent current claimants and a future claimants' representative (the "FCR") to represent future claimants. Once the TCC and the FCR have been appointed and retained their respective professionals, the Debtor will work cooperatively with these representatives toward the goal of a consensual plan.

Both the Debtor and the claimants' representatives will need information to prepare for negotiations and move forward with the case. Therefore, the Debtor expects to engage in early discussions regarding information that the claimants' representatives will need. The Debtor will make every effort to expedite this information gathering process by, among other things, making appropriate information available to the TCC and the FCR without the need for formal discovery, but subject to an agreed-upon protective order. The Debtor also would be willing to explore mediation early in the case.

B. Liability Determination

Consistent with the Debtor's intent to move this case forward from the start, the Debtor intends to promptly ask this Court to begin the process to help determine for plan purposes any talc liability of the Debtor. The Debtor is committed to working with the other parties to manage the discovery process as efficiently as possible. In addition, at all appropriate times the Debtor will be willing to explore settlement opportunities with the TCC and the FCR.

C. Plan of Reorganization

Ultimately, the Debtor's objective is to negotiate and develop a confirmable plan of reorganization that resolves any legitimate talc claims through a trust. Achieving a confirmed plan of reorganization in this chapter 11 case would benefit all parties in interest. The Debtor would benefit from a global resolution of any talc liability in a manner that is fair and equitable. Any legitimate claimants would likewise benefit because the cost, uncertainty, and delay of litigation would be eliminated. Instead, claimants would follow streamlined trust distribution procedures that enable fair compensation payments faster and more efficiently. The Debtor will work with the TCC and the FCR to establish a process for negotiating a plan. Again, the Debtor also is willing to consider mediation if the parties are otherwise unable to reach an agreement.

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Respectfully submitted,

/s/ *John R. Miller, Jr.*

C. Richard Rayburn, Jr. (NC 6357)
John R. Miller, Jr. (NC 28689)
RAYBURN COOPER & DURHAM, P.A.
227 West Trade Street, Suite 1200
Charlotte, North Carolina 28202
Telephone: (704) 334-0891
Facsimile: (704) 377-1897
E-mail: rrayburn@rcdlaw.net
jmiller@rcdlaw.net

Gregory M. Gordon (TX Bar No. 08435300)
Dan B. Prieto (TX Bar No. 24048744)
Amanda Rush (TX Bar No. 24079422)
JONES DAY
2727 N. Harwood Street
Dallas, Texas 75201
Telephone: (214) 220-3939
Facsimile: (214) 969-5100
E-mail: gmgordon@jonesday.com
dbprieto@jonesday.com
asrush@jonesday.com
(Admissions *pro hac vice* pending)

Brad B. Erens (IL Bar No. 06206864)
Caitlin K. Cahow (IL Bar No. 6317676)
JONES DAY
77 West Wacker
Chicago, Illinois 60601
Telephone: (312) 782-3939
Facsimile: (312) 782-8585
E-mail: bberens@jonesday.com
ccahow@jonesday.com
(Admissions *pro hac vice* pending)

PROPOSED ATTORNEYS FOR DEBTOR

Kristen R. Fournier
(NY Atty. ID No. 4439857)
KING & SPALDING LLP
1185 Avenue of the Americas
34th Floor
New York, NY 10036
Telephone: (212) 556-2100
Facsimile: (212) 556-2222
E-mail: kfournier@kslaw.com
(Admission *pro hac vice* pending)

Kathleen A. Frazier (TX Bar No. 24043663)
SHOOK, HARDY & BACON L.L.P.
JPMorgan Chase Tower
600 Travis Street, Suite 3400
Houston, TX 77002
Telephone: (713) 227-8008
Facsimile: (713) 227-9508
E-mail: kfrazier@shb.com
(Admission *pro hac vice* pending)

PROPOSED SPECIAL COUNSEL FOR DEBTOR